



SPECIAL CONDITIONS OF CONTRACT

RT 302-2012

**SUPPLY AND DELIVERY OF SURGICAL SUTURES AND LIGATURES
TO THE STATE
FOR THE PERIOD 1 AUGUST 2013 TO 31 JULY 2015**

**NATIONAL TREASURY
CONTRACT MANAGEMENT**



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ABBREVIATIONS

BAC	: Bid Adjudication Committee
B-BBEE	: Broad Based Black Economic Empowerment
CPA	: Contract Price Adjustment
CPI	: Consumer Price Index
PPI	: Producer Price Index
ROE	: Rate of Exchange
SANAS	: South African National Accreditation System
SBD	: Standard Bidding Document
TCBD	: Transversal Contract Bidding Document
VAT	: Value- Added Tax



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 are supplementary to that of the General Conditions of Contract. Where, however, the Special Conditions of Contract are in conflict with the General Conditions of Contract, the Special Conditions of Contract will prevail.

2 EVALUATION CRITERIA

2.1 *Preference Point System*

2.1.1 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 contribution (maximum 10 points)

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

$$P_s = 90 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where

P_s = Points scored for comparative price of bid under consideration

P_t = Comparative price of bid under consideration

P_{\min} = Comparative price of lowest acceptable bid

2.1.3 A maximum of 10 points may be allocated to bidders for attaining their B-BBEE status level of contribution in accordance with the table below:



B-BBEE Status Level of Contributor	Number of Points
1	10
2	9
3	8
4	5
5	4
6	3
7	2
8	1
Non-compliant contributor	0



- 2.1.4 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, in order to claim the B-BBEE status level points.
- 2.1.5 The points scored by a bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.
- 2.1.6 Only bidders who have completed and signed the declaration part of the bid documentation may be considered.
- 2.1.7 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.
- 2.1.8 The points scored will be rounded off to the nearest 2 decimals.
- 2.1.9 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.
- 2.1.10 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.
- 2.1.11 Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.
- 2.1.12 A contract may, on reasonable and justifiable grounds, be awarded to a bid that did not score the highest number of points.

3 RESPONSE FIELDS

- 3.1 Bidders are required to submit responsive bids by completing all the prices, mandatory response fields and item questionnaires on the provided pricing schedule for the individual items.
- 3.2 Non-compliance with this condition may invalidate the bid for the item(s) concerned.

4 AUTHORISATION DECLARATION

- 4.1 Any bidder who is sourcing goods from a third party must complete the "Authorisation Declaration"



(TCBD 1) in full for all relevant goods, sign it and submit it together with the bid documents at the closing date and time of the bid.

- 4.2 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.
- 4.3 The bidder must ensure that all financial and supply arrangements for goods, including lead times, have been mutually agreed upon between the bidder and the third party. No agreement between the bidder and the third party will be binding on the State.
- 4.4 Failure to submit a duly completed and signed Authorisation Declaration, with the required annexure(s), in accordance with the above provisions may invalidate the bid for such goods offered.

5 TAX CLEARANCE CERTIFICATE

- 5.1 An original and valid Tax Clearance Certificate issued by the South African Revenue Services certifying that the taxes of the bidder are in order must be submitted at the closing date and time of bid.
- 5.2 Failure to submit the original and valid Tax Clearance Certificate may result in the invalidation of the bid.
- 5.3 Copies and/or certified copies of the Tax Clearance Certificate may not be acceptable.

6 VALUE ADDED TAX

- 6.1 All bid prices must be inclusive of 14% Value-Added Tax.
- 6.2 Failure to comply with this condition may invalidate the bid.

7 SUBMISSION OF BIDS

- 7.1 Bidders must submit the bid in hard copy format (paper document) to National Treasury: Tender Information Centre before the closing date and time. The hard copy of the bid response will serve as the legal bid document. The bid must be addressed to the National



Treasury: Tender Information Centre.

7.2 Each bid should 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 must be clearly endorsed.

7.3 Bidders are encouraged to bid electronically via the electronic response system to facilitate the speedy evaluation of bid responses. Electronic bids must also be submitted before the closing date and time. Besides responding electronically through the electronic response system, the bidder is still required to submit a hard copy of the bid document before the closing date and time. In the event that a hard copy of the bid document is not received on or before the closing date and time, the bid will be invalidated.

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

8 LATE BIDS

8.1 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.

9 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.

10 FRONTING

10.1 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.

10.2 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.

11 SUPPLIER DUE DILIGENCE

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

12 COMMUNICATION

12.1 Contract Management together with the National Department of Health 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.

12.2 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.

12.3 All communication between the bidder and the Contract Management Office and the National Department of Health must be done in writing.

13 CONTACT DETAILS

13.1 General

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

Physical address: 240 Vermeulen Street, cnr. Andries- and Vermeulen- Streets, Pretoria



13.2 ***Bid Enquiries***

Contract Manager: Lungile Mavuso/ Patiswa Mgcodo

Contract Management, National Treasury

Tel: (012) 315 – 5914/012-315-5820

Fax: (012) 315 – 5400

E-mail: Lungile.mavuso@treasury.gov.za / Patiswa.mgcodo@treasury.gov.za

13.3 ***Specification / Technical Enquiries***

Pharmaceutical Policy & Planning, Department of Health – Fax No (012) 312-8823

Mrs P Moloko Tel: (012) 395-8439 e-mail: molokp@health.gov.za

Ms M Rasengane Tel: (012) 395-9452 e-mail: rasenm@health.gov.za

13.4 ***Sample Enquiries***

Pharmaceutical Policy & Planning, Department of Health – Fax No (012) 312-8823

Mrs P Moloko Tel: (012) 395-8439 e-mail: molokp@health.gov.za

Ms M Rasengane Tel: (012) 395-9452 e-mail: rasenm@health.gov.za



SECTION B

14 CONTRACT PERIOD

The contract period shall be for a period of 24 months commencing on 01 August 2013 to 31 July 2015.

15 PARTICIPATING GOVERNMENT DEPARTMENTS / INSTITUTIONS

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

National Departments

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

Provincial Departments

- Provincial Departments of Health: Eastern Cape, Free State, Limpopo, Mpumalanga, Northern Cape, North West.

15.2 *Post award participation*

15.2.1 In terms of Treasury Regulation 16A6.6 and Municipal Supply Chain Management Regulation 32, an Accounting Officer/Accounting Authority may, on behalf of a department, constitutional institution, public entity, Municipality 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 BAC for Transversal Contracts and relevant contractors.

16 AWARD CONDITIONS

The State reserves the right to award contracts to more than one contractor, but not more than three, for the same line item. Only bids that are within 20% of the highest bid's total points will be considered for split and multiple awards.



16.1 ***Split Award***

The following formula will be used for the purpose of splitting contracts between **two** contractors:

Category	Difference between points	Recommended percentage split
A	Equal points	50/50
B	0,1 – 5 %	60/40
C	5,1 – 10 %	70/30
D	10,1 – 20 %	80/20

16.2 ***Multiple Award***

For multiple award of the same item to **more than two** contractors (maximum 3), the volume will be proportionately allocated based on total points, provided that the difference in total points between the highest and lowest recommended bidders does not exceed 20 %.

16.3 ***Items grouped as a Series***

16.3.1 All items that are grouped as a series in specification shall be regarded as a group series and be evaluated and awarded accordingly.

16.3.2 Bidders are required to offer prices for all units of measure specified in the series.

16.3.3 Bidders must take note that the allocation of points will be per category (group award).

16.3.4 Non-compliance with the abovementioned special conditions will invalidate the bid for the item/s concerned

16.4 ***Other award conditions***

16.4.1 The State reserves the right to negotiate prices.

16.4.2 The State reserves the right not to award a line item

17 BID INFORMATION SESSION

17.1 A non-compulsory information session will be held at:

National Treasury, 240 Vermeulen Street, Pretoria.

Date: 18 May 2012

Time: 10h00

Venue: Room 0101



- 17.2 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 substantial issues they might have.

18 ADDITIONAL DOCUMENTATION / INFORMATION REQUIRED SPECIFIC TO THIS BID

18.1 *Format and Submission of Bid*

- 18.1.1 Bidders are required to submit their bids in the following manner:-

Section 1	Standard bidding documents
Section 2	Pricing Schedule and Item Questionnaire
Section 3	Product information documents (catalogues, operating manuals, instruction leaflets, etc.)

18.2 *Other information required*

- 18.2.1 Product information documents (e.g. catalogues, operating manuals, instruction leaflets, etc.), in at least the English language, must accompany the bid documents as well as all samples submitted.
- 18.2.2 It is the responsibility of the bidder to provide the participating departments with adequate information on all products

19 PRICING STRUCTURE

- 19.1 Prices quoted must be furnished on the basis of “delivered into store” country-wide
- 19.2 Prices quoted must be per unit of measure as per specification of each item as advertised. Deviating from this condition may invalidate the bid against the relevant item
- 19.3 Bids must be for the supply ex duty paid stocks held in the Republic of South Africa during the contract period.
- 19.4 Prices submitted for this bid must be filled in on the field provided on the pricing schedules supplied with the bid. Price structures that do not comply with this requirement may invalidate the bid.



20 CONTRACT PRICE ADJUSTMENTS

20.1 *Formula*

20.1.1 Prices submitted for this bid will be regarded as non-firm and subject to adjustment(s) in terms of the following formula, defined areas of cost and defined periods of time.

20.1.2 Applications for price adjustments must be accompanied by documentary evidence in support of any adjustment claim.

20.1.3 The following price adjustment formula will be applicable for calculating contract price adjustments (CPA).

$Pa = (1 - V)Pt \left(D1 \frac{R1t}{R1o} + D2 \frac{R2t}{R2o} + D3 \frac{R3t}{R3o} + + Dn \frac{Rnt}{Rno} \right) + VPt$		
Pa	=	The new adjusted price to be calculated
V	=	Fixed portion of the bid price (15% or 0.15)
Pt	=	Original bid price. Note that Pt must always be the original bid price and not an adjusted price
(1-V)Pt	=	Adjustable portion of the bid price (85% or 0.85).
D1 – Dn	=	Each factor (or percentage) of the bid price, e.g., material, labour, transport, overheads, etc. The total of the various factors (or percentages) D1 – Dn must add up to 1 (or 100%).
R1t – Rnt	=	End Index. Index figure obtained from the index at the end of each adjustment period.
R1o–Rno	=	Base Index. Index figure at the time of bidding.
VPt	=	15% (or 0.15) of the original bid price. This portion of the bid price remains fixed, i.e. it is not subject to price adjustment.

20.2 *Formula component definitions*

20.2.1 Adjustable amount

The adjustable amount is the portion of the bid price which is subject to adjustment. In this bid the adjustable amount is 85% of the original bid price. For example, if the bid price is R1000, then only R850 will be subject to adjustment.



20.2.2 Fixed portion

The fixed portion represents those costs which will not change over the adjustment period and DOES NOT represent the profit margin. In this bid the fixed portion is 15% of the original bid price. Using the same example as above, it would amount to R150 which will remain fixed over the contract period.

20.2.3 Cost components and proportions

The cost components of the contract price usually constitute the cost of materials (raw material or finished product), cost of direct labour, cost of transport and those other costs which are inclined to change. The proportions are the contribution to the contract price of each of these cost components. In this bid the following cost components will be used to calculate contract price adjustments.

Bidders are requested to submit the cost breakdown of the bid price for each item with their bid. Should the cost breakdown be the same for all items on the bid, please indicate it clearly in the bid document. Bidders will not be allowed to change the cost breakdown of bid prices during the tenure of the contract.

Successful bidders that are direct importers of raw material / finished product can apply for RoE adjustment under cost element D1. If the successful bidder is not a direct importer of raw material / finished product, cost component D1 would not be applicable and only local cost components (D2 - Dn) would be applicable.

Cost Component	% Contribution
D1- Imported Raw Material / Finished product (if applicable)	
D2 - Local Raw Material / Finished product (if applicable)	
D3 – Labour	
D4 – Transport	
D5 – Other	
TOTAL (Cost components must add up to 100%)	100 %

20.2.4 Applicable indices / references

The applicable index refers to the relevant market index, which is a true reflection of price movement(s) in the cost over time. In this bid the following indices or reference will be applicable:



Cost component	Index Publication	Index Reference
D1 – Imported Raw Material / Finished product (if applicable)	Supplier / Manufacturer invoice(s) and remittance advice. ¹	Documentary evidence to accompany claim.
D2 - Local Raw Material / Finished product (if applicable)	STATS SA P0142.1 (PPI) Table 8 – Domestic Output OR Supplier / Manufacturer invoice(s) ²	Compound Chemical Product – Pharmaceutical Products OR Documentary evidence to accompany claim
D3 – Labour	STATS SA P0141 (CPI), OR Labour agreement ³	Table E - All Items or Relevant table OR Labour agreement to be provided
D4 – Transport	STATS SA P0141 (CPI)	Table E - Transport – Other Running Cost
D5 – Other	Specify	Documentary evidence to accompany claim

20.2.5 Base Index Date

The base index date applicable to the formula is defined as the date at which the price adjustment starts. In this bid the base index date is May 2012.

20.2.6 End Index Date

The end index dates are the dates at predetermined points in time during the contract period. In this bid the end indices are defined in the next paragraph (Price Adjustment Periods).

¹ In cases where invoices are supplied as documentary evidence, it is advised that invoices closest to the Base Index date and the End Index date be submitted. It should ideally reflect the adjustment period.

² Same as footnote 1.

³ In the absence of a labour agreement, the labour cost component will be adjusted with CPI Headline inflation.



20.2.7 Price Adjustment Periods

Adjustment to contract prices may be applied for at the following dates:

Adjustment	CPA application to reach the office at the following dates	End Index Date	Dates from which adjusted prices will become effective	Dates until which adjusted prices will be effective
1 st Adjustment	4 September 2013	July 2013	1 October 2013	31 March 2014
2 nd Adjustment	5 March 2014	Jan 2014	1 April 2014	30 September 2014
3 rd Adjustment	3 September 2014	July 2014	1 October 2014	31 March 2015
4 th Adjustment	6 March 2015	Jan 2015	1 April 2015	31 July 2015

20.3 ***Rates of Exchange (RoE) – Base and Average rates***

In the event where material and/or finished products are imported the following will apply:

- 20.3.1 The formula described above will be used and the imported cost component of the bid price (D1) will be adjusted taking into account the base RoE rate (refer paragraph 21.3.4) and the average RoE rate over the period under review indicated in paragraph 21.3.6 below.
- 20.3.2 In the event where the RoE adjustment goes hand in hand with a material/product price increase, the material/product price (in foreign currency) will be converted to South African currency using the base rate (paragraph 21.3.4) for the earlier invoice and the average RoE rate for the period under review as indicated in paragraph 21.3.6 below for the later invoice.
- 20.3.3 The imported cost component (D1) will be adjusted together with all the other cost components indicated in paragraph 21.2.3 and 21.2.4 above and at the predetermined dates indicated in paragraph 21.2.7 above.
- 20.3.4 Rate(s) of exchange to be used in this bid in the conversion of the bid price of the item(s) to South African currency is indicated in the table below.



Currency	Rates of exchange 6 month average for the period (5 September 2011 to 5 May 2012)
US Dollar	7.8718
Pound Sterling	12.4030
Euro	10.4992
Yen	9.9852

20.3.5 Should the bidder make use of any other currency not mentioned above, the bidder is requested to calculate the average for the period 5 September 2011 to 4 May 2012 20 October 2011 to 20 April 2012 using the Reserve Bank published rates for the specific currency. Visit www.reservebank.co.za to obtain the relevant rates. Please refer to TCBD 2 (Procedure to download historical exchange rates from the Reserve Bank website) for instructions.

20.3.6 Contract price adjustments due to rate of exchange variations are based on average exchange rates as published by the Reserve Bank for the periods indicated hereunder:

Adjustment	Average exchange rates for the period:
1 st Adjustment	1 June 2012 to 31 August 2013
2 nd Adjustment	1 September 2013 to 28 February 2014 30 April 2013
3 rd Adjustment	1 March 2014 to 31 August 2014
4 th Adjustment	1 September 2014 to 28 February 2015

20.4 **General**

20.4.1 Unless approval has been obtained from Contract Management, no adjustment in contract prices will be made.

20.4.2 Applications for price adjustment must be accompanied by documentary evidence in support of any adjustment.

20.4.3 CPA applications will be applied strictly according to the specified formula and parameters above as well as the cost breakdown supplied by bidders in their bid documents.



- 20.4.4 In the event where the supplier's CPA application, based on the above formula and parameters, differs from Contract Management's verification, Contract Management will consult with the supplier to resolve the differences.
- 20.4.5 Bidders are referred to paragraph 9 of the Special Conditions regarding Counter Conditions.
- 20.4.6 An electronic price adjustment calculator will be available on request from Contract Management.

21 PRE-AWARD PRODUCT COMPLIANCE

The following pre-award product compliance will apply:

21.1 Specifications

- 21.1.1 Items must comply with item specifications as stated in the bid document.

21.2 Standards

- 21.2.1 Items must comply with Standards as stated in the item specification.

- 21.2.2 South African Bureau of Standards (SABS):

SANS, SABS, ISO AND CKS specifications are available from South African Bureau of Standards Offices countrywide. Obtaining of such specifications will be the responsibility of and for the account of the prospective bidder. To purchase standards, obtain quotes or enquire about the availability of e-Standards, please contact Standards Sales at:

Postal Address: Private Bag X191, Pretoria, 0001

Physical Address: 1 Dr Lategan Road, Groenkloof, Pretoria

Tel:(012) 428 6883, Fax: (012) 428 6928, E-mail: sales@sabs.co.za

Website: www.sabs.co.za and follow the "Search/Buy Standards" link



21.2.3 *South African National Accreditation System (SANAS):*

The contact details of SANAS are as follows:

Postal Address: Private Bag x 23, Sunnyside, Pretoria, 0132

Physical Address: The DTI Campus, 77 Meintjies Street, Sunnyside, Pretoria, 0002,

Tel: 012-394 3760, Fax: 012-3940526

A list of institutions is available on the SANAS website <http://www.sanas.co.za/> or <http://www.sanas.co.za/contact.php>

21.3 ***Submission of Samples for User and Physical Evaluation***

21.3.1 All bidders, including current contractors are required to submit samples of all items from 04 May 2012 between 08:00 – 15:00 until 15-June-2012.

21.3.2 SAMPLES must be submitted to both the following venues:

Free State Pharmaceutical Supply depot

23 Blignaut Street

Hilton BLOEMFONTEIN

9302

Contact Person: Ms K Mosakire

Telephone: (051) 411 0562

AND

Eastern Cape Pharmaceutical depot

Struanway

Struandale,

Port Elizabeth

6001

Contact person: Mr Deon Martin

Telephone: (041) 406 9826 / 9834



21.4 *Criteria for sample submission*

21.4.1 Samples will ONLY be accepted within the above period and timeframe. No samples will be accepted after the date and time as indicated in paragraph 22.3.1.

21.4.2 Where different sizes of the same product are called for against different item numbers, samples of each size must be submitted.

21.4.3 All samples submitted must be a true representation of the product which will be supplied. Samples for each item offered on tender must be in the original sealed pack (e.g. a box of 12 sutures) to each of the above facilities.

21.4.4 Bidders must ensure that samples submitted at the two facilities for user and physical evaluation must be from the same batch number and must not have an expiry date of less than one (1) year. Should the samples pass the user and physical evaluation; bidders will be required to submit samples, from the same batch as above, to SABS for testing.

21.4.5 Bidders must ensure that samples submitted at the two facilities for user and physical evaluation must be from the same batch number and must not have an expiry date of less than one (1) year. Samples from the same batch are to be submitted to SABS when requested to do so in accordance with paragraph 22.4 below

21.4.6 Bids not supported by samples may invalidate the bid for the item(s) for which samples are not submitted.

21.5 *Marking and submission of samples*

21.5.1 Samples must be clearly marked on the outside with the bid number, item number, and the bidder's name. This detail must appear on a label attached to each individual box.

21.5.2 Failure to comply with this condition may invalidate the bid against the relevant item.

22 EVALUATION PROCESS

The evaluation process comprises the following phases:

22.1 *Phase I - Initial screening process:*

During this phase bid documents will be reviewed for completeness and to determine compliance with all mandatory requirements.



22.2 ***Phase II –User and Physical Evaluation of Samples***

During this phase all samples submitted to the designated institutions will be subject to independent user and physical evaluation to determine compliance to specification and user usability.

The two designated institutions will compile independent reports of the evaluation results and submit the reports to the Bid Evaluation Committee.

The BEC will review the reports and recommend all pre-qualified items to be sent for further testing at a SANAS accredited testing institution

22.3 ***Phase III – Points Evaluation Criteria***

During this phase all responsive bids will be evaluated in terms of the preference point system as per paragraph 2 of this document.

22.4 ***Phase IV –Submission of samples for testing to a SANAS accredited institution for compliance to SANS 494-1 (2011 Edition)***

During this phase preferred bidders will be notified to submit samples to a SANAS accredited testing institution. The details of the submission of samples will be contained in the notification to the preferred bidders.

Bidders will be required to submit samples to the SABS for testing. The samples to be submitted to the SABS should be from the same batch as those indicated in paragraph 21.4.5

Sample testing will be for the account of the Bidder. The testing institution will provide the test reports to the relevant Bidder, with copies to the National Department of Health and National Treasury.

It should be noted that by submitting samples for testing the bidders consent that the testing institution releases the test results to Contract Management, National Treasury and National Department of Health.

22.5 ***Phase V – Bid Evaluation Committee Meeting (BEC) Recommendations***

The BEC will conduct the final consideration of all the results coming out of all the above phases and will recommend to the BAC for Transversal Contracts for adjudication and award.



23 DELIVERY AND QUANTITIES

23.1 *Delivery Basis*

- 23.1.1 Firm lead times for delivery of not more than 6 weeks must be quoted for the duration of the contract period.
- 23.1.2 Transit and storage conditions applicable to the relevant product must be adhered to.

23.2 *Quantities*

- 23.2.1 The quantities reflected in the bid forms are estimated quantities and no guarantee is given or implied as to the actual quantity which will be procured during the contract period.
- 23.2.2 The quantity indicated against each item represents the total estimated off-take of all participating departments. A breakdown of the national estimate into participating Government Departments and Provincial Administrations can be referenced in the addendum provided.

24 PACKAGING

24.1 *General*

- 24.1.1 All deliveries made against this contract, in all modes of transport, are to be packed in suitable containers, which will be acceptable for further dispatch. Attention is drawn to the requirements of the Transnet Freight Rail Standard Conditions of Carriage Policy
- 24.1.2 The packing of the goods to be supplied must be uniform for the duration of the contract period, i.e.:
- The number of units per commercial packing.
 - The number of commercial packs per carton.
 - The number of cartons per bulk packing.
 - The name and quantity of the contents and expiry date if applicable must appear clearly on the packing.
 - All containers, packing and cartons must be clearly labelled.
 - All products must be packed in acceptable containers, where applicable, specifically developed for the product allowing safe stacking.
 - The conditions under which the product must be stored.



- Date of manufacture and expiry must be clearly shown.

24.2 **Containers**

24.2.1 The function of a container for medical related substances is to maintain the quality, safety and stability of its contents. Containers should withstand the mechanical hazards of handling, transport and storage, prevent leakage, and provide an appropriate level of protection from environmental conditions or contact with metal where relevant.

24.2.2 Conditions of the container must be acceptable to the purchaser at the point of delivery. The container materials should have no chemical or physical effect on the product. BPC 1973 p. xxxvi and p 642.

24.3 **Bulk Packing**

24.3.1 The pallet system in bulk is preferred with the following criteria:

- Maximum pallet size 1,2m x 1m
- Maximum mass a 1000kg/pallet
- Pallet material used must be of such good quality as to withstand normal mechanized handling
- Maximum single packed pallet total height 80 cm.
- Maximum single stacking height 4m.
- Side delivery from transport is used. Special reference is made to the containerization principle.

25 **LABELS AND PRODUCT INFORMATION**

25.1 **General**

25.1.1 The following information must be clearly and indelibly printed on all inner and outer packaging in at least English:

- Name of the product
- A Product code as relevant
- The trade name or trademark of the manufacturer;
- Size of the product
- Quantity of the contents
- Name of manufacturer



- Date of manufacture
- Name and address of importer/distributor (if not manufacturer)
- Expiry date
- Batch/lot number. Products must have the same batch/lot number on the outer box as on the inner box.
- The word “sterile” and the method of sterilization

25.2 ***Peel Apart Packs***

25.2.1 The material and design of a peel-apart (unit) pack shall be such as to ensure:

- easy opening with the fingers;
- maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;
- minimum risk of contamination of the contents during opening and removal from the package
- adequate protection of the contents during normal handling, transportation and storage;
- that once opened, the package cannot be easily re-sealed, and it shall be obvious that the unit package has been opened; and
- that a peel-apart pack shall tear cleanly without the formation of loose fluff or loose fibres.

25.2.2 Both the content and the immediate package shall be sterile and shall comply with the requirements of the "Sterility tests" given in the latest version of the USP (United States Pharmacopeia)

26 **SHELF LIFE**

26.1 Where applicable, products, upon delivery must have at least 18 months of shelf-life before date of expiry.

26.2 Contractors may make written applications to the purchasing institution to deliver goods with a shorter shelf-life, provided such applications are accompanied by an undertaking that unused short- dated stock shall be unconditionally replaced before or after expiry.

26.3 Any delivery of short dated supplies without prior written approval must be collected by the respective suppliers at their own cost.

26.4 Any participating institution may, without prejudice, decline written applications to deliver short



dated stock.

27 QUALITY

27.1 Where specific specifications and/ or standards, e.g. SABS, SANS, EU, ADA, CKS, BP, BPC, USP, USNE, EP, ISO or DIN, are applicable on materials and supplies, the quality of products shall not be less than the requirements of the latest edition of such specifications and/or standards.

27.2 *Sterility*

27.2.1 Sterilization processes used for medical devices shall comply with the requirements of the following standards, as relevant:

- SANS 11135-1/ISO11135-1, Sterilization of healthcare products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- SANS 11137-1/ISO 11137-1, Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- SANS 10213, The installation and safe use of ethylene oxide (EO) sterilizers in health-care facilities and in industry.

27.2.2 All sterilized products shall be individually packed or in unit packages sterilizable by the method(s) stated by the manufacturer.



SECTION C

28 ROLES AND RESPONSIBILITIES

28.1 ***Contract Administration***

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

The Chief Directorate: Contract Management, National Treasury, Private Bag X115, Pretoria, 0001

And copy to:

The Chief Director: Pharmaceutical Policy and Planning, Department of Health, Private Bag X828, PRETORIA 0001

28.1.2 Contractors must advise the Chief Directorate: Contract Management, National Treasury and The Chief Director: Pharmaceutical Policy, Department of Health immediately when the execution of the contract will be adversely affected. Full particulars of such circumstances as well as the period of delay must be furnished.

28.2 ***Placement of Orders and Payments***

Orders will be placed by participating departments who will be responsible for the payment to contractors for goods delivered and/or services rendered.

28.3 ***Supplier Performance Management***

Supplier performance management will be the responsibility of end-user departments. The National Department of Health will monitor supplier performance. Where supplier performance is sub-optimal and where supplier performance disputes cannot be resolved between the contractor and the relevant purchasing institution, National Treasury: Contract Management must be informed for corrective action.



29 ORDERS AND DELIVERY

29.1 Orders

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

29.1.2 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).

29.1.3 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.

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

29.1.5 The State also reserves the right to purchase its requirements elsewhere outside the contract if –

- The minimum packing or minimum order quantity specified by the contractor be more than that of an institution's requirements
- The item(s) are urgently required and not immediately available
- An emergency arises

29.2 Delivery Adherence

29.2.1 Delivery of goods must be made in accordance with the instructions appearing on the official order forms issued by purchasing institutions.

29.2.2 All deliveries or dispatches must be accompanied by a delivery note stating the official order number against which the delivery has been effected.

29.2.3 In respect of items awarded to them, contractors must adhere strictly to the delivery lead times quoted in their bids..

29.2.4 Deliveries not complying with the order forms will be returned to the contractor at the contractor's expense.



30 PRODUCT ADHERENCE / BRAND CHANGE

- 30.1 In the event where a bidder offers a specific brand against an item and the item is subsequently awarded to the bidder, it is required of the successful bidder to continue to supply the brand awarded throughout the contract period.
- 30.2 In the event that the brand is discontinued, National Treasury, Contract Management and Pharmaceutical Policy and Planning, Department of Health must be notified immediately.
- 30.3 Contractors are not allowed to deliver a different brand other than the brand awarded to them unless approval of brand change has been obtained from the National Department of Health and a communication in this regard has been received from National Treasury, Contract Management.

31 POST-AWARD PRODUCT COMPLIANCE PROCEDURES

The following post-award product compliance procedures will apply:

31.1 Consignment /Batch Testing

- 31.1.1 Consignments (products) must be inspected on a batch to batch basis to ensure continued adherence to the set SABS Standard.
- 31.1.2 Suppliers must submit a batch-representative sample (not less than 24 strings) in original packs to the SANAS accredited or recognized Testing Authority for batch testing.
- 31.1.3 Suppliers should submit a batch-specific report from the SANAS accredited or recognized testing authority to the Chief Directorate: Medicines Policy and Planning, National Department of Health, for every new batch supplied to the purchasing authorities. The National Department of Health will circulate a list of all approved batches to the participating Provincial Departments.
- 31.1.4 In the event that medical devices supplied during the contract period are reported by the end user(s) to be defective, samples from the batch supplied to the end user(s) shall be submitted by the end user(s) to the SANAS accredited or recognized testing agency for testing:
- The samples tested shall be compared to the reference sample originally submitted to the SANAS accredited or recognized testing agency for the bid.
 - Should the defective sample differ from the reference sample, the contractor shall be responsible for the cost of testing.



- Should the defective sample not differ from the reference sample, the end user(s) shall be responsible for the cost of testing.

31.1.5 Bidder's attention is drawn to paragraph 8 of the General Conditions of Contract regarding inspection, tests and analysis.

31.1.6 If the delivered supplies are not in accordance with the contract requirements, the cost of inspections, tests and analysis done by an independent testing facility shall be defrayed by the contractor.

32 PRODUCT INFORMATION

32.1 It is required that contractor(s) provide product information documents (e.g. catalogues, operating manuals, instruction leaflets, etc.), in at least the English language to all participating departments within one month of the commencement of the contract.

33 POST AWARD REPORTING AND MONITORING

33.1 *Historical Data*

All successful bidders are required to submit historical value and volume reports via e-mail to:

- i. Contract Management, National Treasury on a **six** monthly basis:
Lungile Mavuso (lungile.mavuso@treasury.gov.za) / Patiswa Mgcodo
(Patiswa.Mgcodo@treasury.gov.za)
and
- ii. National Department of Health on a **three** monthly basis
Wanda Wolmarans, (wolmaw@health.gov.za)
and
Mamma Rasengane (resenm@health.gov.za).

For this purpose electronic templates will be supplied to successful bidders.

Period	Dates at which reports must be submitted
1	3 February 2014
2	4 August 2014
3	5 February 2015
4	6 August 2015



END