health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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HM01-2012CNDM/02: SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD UP T0 31 MARCH 2015

1. The attached contract circular 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 1of 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 the Contract, the Special Conditions will prevail.

3. The price 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 PERSONS	TEL NO	FAX NO
National Department of Health	T Chidarikire – Director HIV Prevention E Marumo – (Condom contact) M Motsepe – (Condom contact)	(012) 395-9153 (012) 395 9142 (012) 395 9234	086 632 2443 086 632 8758 086 632 5709
Eastern Cape	X Somahela – Hast Manager L Ncala – (Condom contact)	(040) 608 1223 (040) 608 1749	040 609 8401 086 609 1593
Free State	Y Tsibolane – Hast Manager S Boleme – (Condom contact)	(051) 408 1429 (051) 409 1119	(051) 409 8493 (051) 409 8493
Gauteng	N Mmope – Hast Manager N Nyandeni – (Condom contact) M Matlhoko – (Condom contact)	(011) 355 3340 (011) 355 3421 (011) 355 3180	011 355 3338 011 355 3338 011 355 3338
Kwa Zulu -Natal	Dr T Mayise – Hast Manager T Buthelezi – (Condom contact)	(033) 341 4001 (033) 341 4000	086 610 2012 084 556 6885

PARTICIPANTS	CONTACT PERSONS	TEL NO	FAX NO
Limpopo	E Kobola – Hast Manager	(015) 293 6536	086 215 6361
	E Diketane – (Condom contact)	(015) 293 6587	086 215 3913
Mpumalanga	E Nkosi – Hast Manager	(013) 766 3442	(013) 766 3470
	V Nkosi – (Condom contact)	(013)766 3275	(013) 766 3470
	L Nkosi – (Condom contact)	(013) 766 3044	(013) 766 3470
North West	T Isaacs – Hast Manager	(018) 397 2601	(018) 387 2600
	V Salman – (Condom contact)	(018) 397 4073	(018) 387 2600
	K Tlatsana – (Condom contact)	(018) 387 2667	(018) 387 2600
Northern Cape	B Baitsewe – Hast Manager	053) 830 0524	(053) 833 3814
	M Motlhaudi – (Condom contact)	(053)830 0517/	(053) 833 3814
	P Masekwane – (Condom contact)	(053) 830 0517	(053) 833 3814
Western Cape	J Arendse – Hast Manager	(021) 483 3334	(021) 483 6033
	M Dyeshana – (Condom contact)	(021) 483 6893	(021) 483 6033
	L Najjaar – (Condom contact)	(021) 483 9881	(021) 483 6033

K. Jamaloodien

K JAMALOODIEN
DIRECTOR: AFFORDABLE MEDICINES
For: DIRECTOR-GENERAL: HEALTH
DATE: 01/12/2014

HM01-2012/02: SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD UP T0 31 MARCH 2015

1. IMPORTANT GENERAL INFORMATION:

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

1.2 All prices are inclusive of 14 % VAT.

1.3 All prices are on a delivered basis.

1.4 Should an order be placed by any institution other than the provincial medical depots, the validity of the order must first be confirmed with the relevant depot manager.

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	Supplier Address	Contact Detail --- Telephone Number Fax Number	Contact Person E-mail Address
Barrs Medical (Pty) Ltd	VBDD8	Po Box 7348 Roggebaai 8012	Tel: (021) 531 6601 Fax: (021) 531 6727	Joe Morris joe@qualitycondoms.co.za
Endomed Medical& Surgicals (Pty) Ltd	V4890	PO Box 72376 Mobeni 4060	Tel: (031) 791 2230 Fax: (031) 791 2231	Eugene Moodley dbn@endomed.co.za

Item No	Description	Quantity Awarded	Bidder Name	Supplier Code	Brand Name	Delivered Price in ZAR	Unit Pack	Shipper pack	Lead Time (21 Days)	MOQ	Total Score	National Stock Number	Unit of Measure
3	Latex Male Condoms Coloured : Strips of 4 (Pack of 200) Note that full item specification should be read in Annexure A	25,000,000 purple (grape) 125,000 x 200	Barrs Medical (Pty) Ltd	V4890	Choice	R 77.6900	1 x 200	200	10 - 15	60 x 200	90.00	181919701	BX
		25,000,000 purple (grape) 125,000 x 200	Endomed Medical and Surgical Supplies cc	VBDD8	Feel ™	R 86.2700	1 x 200	200	10	1 case (30 boxes)	88.06	181919701	BX

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Special Requirements and Conditions of Contract

HMO1-2012CNDM/02

SUPPLY AND DELIVERY OF MALE AND FEMALE CONDOMS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD UP TO 31 AUGUST 2014

VALIDITY PERIOD 120 DAYS

National Department of Health

Contents

1. SPECIAL CONDITIONS OF CONTRACT

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

Preference Points System

a. 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 Department of Health 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)

Broad Based Black Economic Empowerment (B-BBEE) status level of contributor (maximum 10 points)

b. 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

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	8
4	5
5	4
6	3
7	2
8	1
Non-compliant contributor	0

c. Bidders are required to complete the preference claim form (SBD 6.1) in order to claim the B-BBEE status level points.

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

e. Only bidders who have completed and signed the declaration part of the tender documentation may be considered.

f. The 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.

g. The points scored will be rounded off to the nearest 2 decimals.

h. 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.

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

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

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

l. The Department of Health reserves the right **not** to award a line item.

3. PRE AWARD SUPPLIER DUE DILIGENCE

The Department of Health reserves the right to conduct supplier due diligence prior to final award. This may include site visits.

4. PARTICIPATING AUTHORITIES

The National Department of Health and the following Provincial Departments will participate in this contract:

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

5. CONTRACT PERIOD

The contract period shall be for a period **up to 30 November 2014.**

6. RESPONSE FIELDS

It is imperative that bidders submit responsive bids by completing all the mandatory response fields for the individual items. In this regard bidder's attention is drawn to the response field and price structure explanations and examples supplied in the bid document.

Non-compliance with this condition may invalidate the bid for the item/s concerned**.**

7. VALUE ADDED TAX

All bid prices must be inclusive of 14% Value-Added Tax.

Failure to comply with this condition may invalidate the bid

8. TAX CLEARANCE CERTIFICATE

An original and valid Tax Clearance Certificate issued by the South African Revenue Services certifying that the tax affairs of the bidder are in order must be submitted at the closing date and time of bid.

Copies or certified copies of the Tax Clearance Certificate will not be acceptable. Failure to comply with this condition will invalidate the bid.

9. AUTHORISATION DECLARATION AND DOCUMENTATION OF UNDERTAKING

9.1 DECLARATION OF AUTHORISATION

a. In the event of the bidder not being the actual manufacturer and will be sourcing the product(s) from another company (third party), a signed letter from the source company to the bidder committing to firm supply arrangement(s) for each item, including lead times in this regard, must accompany your bid at closing date and time. The Bid Authorization Form (Form AD1) must be completed and signed giving full details of the declaration of authorisation and be submitted with bid documents at the closing date and time of the bid.

b. The said company/manufacturer/supplier issuing such a letter must confirm that it has familiarised itself with the item description/specification, lead times and bid conditions and if the bid consists of more than one item, it should be clearly indicated in respect of which item(s) the supportive letter has been issued.

c. The Department 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 Department of Health will exercise any of the remedies available to it in the bid documents.

d. 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 Department of Health.

e. It must be indicated in the letter that all the terms and conditions are mutually agreed upon.

f. 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.

9.2 DOCUMENTATION OF UNDERTAKING AND LEGISLATIVE REQUIREMENTS

a. 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.

Bidders must submit a copy of the actual patent or an agreement with the patent holder with the bid document at the closing date and time of the bid.

b. With respect to the female condom, the bidder must supply complete documentation indicating that the product offered has World Health Organisation (WHO) Female Condom Technical Review Committee recommendation

c. Bidders must comply with legal requirements.

9.3 NON COMPLIANCE

Non compliance with the above mentioned (Paragraphs 9.1 and 9.2) special conditions may invalidate the bid for such products offered.

10. CONTRACT ADMINISTRATION

a. Successful bidders must advise the Cluster Manager: Pharmaceutical Policy and Planning 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 within a week of identifying such a problem.

b. The administration and facilitation of the contract will be the responsibility of National Department of Health and all correspondence in this regard must be directed to one of the following addresses:

Director: Affordable Medicine

Department of Health

Postal: Private Bag X828 Pretoria 0001

Physical: Room 501 South Tower 242 Struben Street Pretoria 0001

and

Director: HIV & AIDS and STI's Prevention Strategies

Department of Health

Postal: Private Bag X828 Pretoria 0001

Physical: Room 501 North Tower 242 Struben Street Pretoria 0001

c. The 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.

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

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

11. COUNTER CONDITIONS

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

12. FRONTING

a. The National Department of Health 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 Department of Health condemns any form of fronting.

b. 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 ten years, in addition to any other remedies the National Department of Health may have against the bidder / contractor concerned.

13. PRODUCT COMPLIANCE

13.1 PRE AWARD PRODUCT COMPLIANCE PROCEDURES

The following pre-award product compliance procedures will apply:

a. Compliance to specifications as stated in the bid document.

b. Compliance certificates.

c. A copy of the complete documentation “SABS permit to Apply Certificate Mark” , (i.e not a face sheet but all additional documentation including the precise manufacturing process(es) that the certificate mark applies to).

d. A copy of complete documentation of World Health Organization (WHO) Female Condom Technical Review Committee recommendation as relevant.

e. Submission of samples of the relevant products on or before the closing date and time of the bid at the addresses indicated in paragraph 16.

14. PRICE QUALIFICATION AND CONTRACT PRICE ADJUSTMENT PROCEDURE

14.1 PRICING STRUCTURE

a. Prices submitted for this bid will be regarded as firm and not subject to review.

b. Bidders should quote a final delivered price.

c. Prices quoted must be furnished on the basis of “delivered into store” country-wide

d. Bids must be for the supply ex duty paid stocks held in the Republic of South Africa during the contract period.

e. Prices quoted must be per unit as per specification of each item as advertised.

f. Prices submitted for this bid must be entered on the relevant fields on the bid response document.

g. Price structures that do not comply with this requirement may invalidate the bid.

14.2 PRICE ADJUSTMENTS

a. There will be no price adjustment.

b. Bidders are required to complete the price breakdown in the relevant response fields as per diagram below..

Cost component (For fully imported or finished products offered from another manufacturer, materials and manufacturing components may be combined)		**% of total product value** (values in this column must add up to 100%)	**Value** (Value for "% imported" and "% local" must add up to 100% for each cost component)	
			% imported	**% local**
Cost of raw materials				
Manufacturing cost	Labour			
	Other			
Transportation cost	Fuel		N/a	
	Freight			
Margin			N/a	N/a

14.3 PRICE ADJUSTMENT PERIODS

No adjustment to contract prices will be applied

14.4 RATES OF EXCHANGE (RoE) – BASE AND AVERAGE RATES

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

a. Rate(s) of exchange to be used in this bid in the conversion of the price of the item(s) to South African currency.

Currency	**Rates of exchange** Average for the period 01 August 2013 to 31 January 2014.
US Dollar	R10.2392
Pound Sterling	R 16.4580
Euro	R13.8452

b. 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 01 August

2013 to 31 January 2014 using the South African Reserve Bank published rates for the specific currency. Visit www.reservebank.co.za to obtain the relevant rates.

c. 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:

14.5 GENERAL

a. Unless prior approval has been obtained from National Department of Health, no adjustment in contract prices will be made.

b. Contract Price Adjustment (CPA) applications will be applied strictly according to the specified formula and variables above as well as the cost breakdown supplied by successful bidders in their bid documents.

c. In the event where the supplier's CPA application, based on the above formula and parameters, differs from National Department of Health's verification, National Department of Health will consult with the supplier to resolve the differences.

d. Bidders are referred to paragraph 11 of the Special Conditions regarding counter conditions.

e. An electronic price adjustment calculator will be made available on the Department of Health's website and will be communicated.

15. QUANTITIES, ORDERS AND DELIVERY

15.1 DELIVERY ADHERENCE

a. For each product, bidders must explicitly indicate in the response fields the minimum and maximum volumes that they can supply on a monthly, quarterly (3-monthly) and annual basis

b. Sufficient stocks must be stored in a warehouse in South Africa to meet delivery requirements as per paragraph 28. Ability to supply must be maintained throughout the duration of the contract.

c. Bidders must indicate and provide assurance of ability to maintain delivery lead time (time from placement of the order to delivery at the identified delivery point) for the duration of the contract in compliance with paragraph 28.

d. Delivery of products must be made in accordance with the instructions appearing on the official order forms emanating from the above mentioned Participating Authorities and institutions placing the orders.

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

f. In respect of items awarded to them, contractors must adhere strictly to the delivery periods quoted by them in their bids.

g. The instructions appearing on the official order form regarding the supply, dispatch and submission of invoices must be strictly adhered to.

h. All invoices should be delivered / posted to reach the institution that placed the order timeously. The invoices should be original and accompanied by proof of delivery.

i. Deliveries must be in accordance with official orders and any deviation will be returned to the contractor at the contractor's expense.

j. Deliveries must conform to cold chain distribution requirements, if applicable. Normal storage conditions (25 degrees Celsius) must not be exceeded.

15.2 QUANTITIES AND ORDERS

a. The ordered quantities are required for delivery as indicated by the particular participating departments.

b. Suppliers should under no circumstances deviate from the orders issued by the departments.

c. The Department of Health is under no obligation to purchase any stock, which is in excess of the indicated quantities for any item.

d. The quantity indicated against each item represents the total estimated off-take of all participating departments as per paragraph 4.

e. Bidders should note that the order/s will be spread out throughout the contract period and that delivery points will be to the individual Provincial Depots or institutions.

f. Bids must be for supply ex duty paid stocks held in the Republic of South Africa during the contract period.

g. The quantities reflected in the bid documents are estimated quantities and no guarantee is given or implied as to the actual quantity which will be ordered.

h. The Department of Health also reserves the right to purchase its requirements elsewhere outside the contract in terms of clause 21 of the General Conditions of Contract if:

- Minimum order quantity specified by the contractor be more than that of the purchaser's requirements
- The item(s) are urgently required and not immediately available

- An emergency arises
- If the contractor fails to perform in terms of this contract

i. The Department of Health reserves the right to arrange contracts with more than one contractor for the same item but not exceeding ten contractors subject to the following condition:

- In a split or multiple award a single bidder will not be awarded more than one portion for the same line item.
- The Department of Health reserves the right not to split award amongst bidders using the same source and / or manufacturer.

j. The allocation of volumes between two suppliers will be determined based on the difference in points, as follows:

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

k. The Department of Health reserves the right to determine the number of awards per line item.

l. For multiple awards of the same item to three or more bidders the volume will be allocated according to the following formula in line with paragraph 15.2 k:

Supplier portion = [1/N * 100]% + [Supplier score – Mean score] * 2.3 %

where N= the number of bids accepted.

m. The Department of Health reserves the right to invite bids on supplementary tender should it be necessitated by developing circumstances.

15.3 MANUFACTURING INFORMATION

Bidders must disclose the manufacturing site(s) as well as suppliers of raw material.

Bidders must be able to substantiate their bid price.

16. SAMPLES

a. Do not submit samples to the National Department of Health.

b. Where a standard is indicated, a sample must be submitted for testing to SABS before the closing date and time of bid. The purpose is to obtain a test report for the items being offered in the bid.

c. 1200 pieces per batch of male condoms and 1200 pieces per batch of female condoms including sampling certificate from accredited independent sampling organisation must be submitted for testing before the closing date and time of the bid.

d. Proof from the SABS of submission of samples must be submitted with the bid at the closing date and time of bid

e. Samples will not be accepted after the closing date and time of bid.

f. Test reports must be submitted with the bid at closing time and date of bid proving that the relevant item(s) complies with the specification after inspection and testing of the samples by SABS.

g. In the event that a test report cannot be obtained from the testing institution prior to the closing date and time of the bid, the bidder must obtain proof (issued by the testing institution) that the sample had been submitted to the testing institution for testing before or on the closing date and time of the bid. Such proof must be submitted with the bid at closing date and time of the bid. Failure to provide such proof may invalidate the bid.

h. All bidders, including current contractors, are required to submit samples.

i. Condom samples will be evaluated for design and performance criteria in compliance with product specifications and World Health Organisation standards. No evaluation of foil design and packaging will be carried out prior to the closure of the bid.

j. It is imperative that samples of all items offered be submitted for evaluation.

k. During the bidding process bidders are accountable for the cost of testing.

l. Samples to be submitted at the address indicated below:

South African Bureau of Standards
1 Dr Lategan Road
Groenkloof
Contact Person: Ms Isabella Masemola
Tel: (012) 428 6131

m. Marking of samples for submission to testing institutions should be done according to the following requirements:

- Samples must be placed in suitable containers and be clearly marked on the outside with the bid number(s), and the bidder’s name.
- Branding is not required for samples submitted for testing.

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

17. STANDARDS FOR TESTING OF SAMPLES

a. Items must comply with standards as stated in the bid documents.

b. South African Bureau of Standards:

SANS, SABS, ISO AND CKS specifications are available from South African Bureau of Standards Office's countrywide. Obtaining such specifications will be the responsibility of and for the accounts of the prospective bidder. To purchase standards, obtain quotes or enquire about the availability of eStandards, 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

c. South African National Accreditation System (SANAS):

The contact details of SANAS are as follows:

Postal Address: Private Bag X23, Sunnyside, Pretoria, 0132
Physical Address: The DTI Campus, 77 Meintjies Street,
Sunnyside, Pretoria, 0002,
Tel: (012) 394 3760, Fax: (012) 394 0526
A list of institutions is available on the SANAS website
http://222.sanas.co.za/ or http://www.sanas.co.za/contact.php

d. Manufacturers and suppliers of male and female condoms shall follow an appropriate code of quality management, including good quality management system as required in the manufacturing and packaging of condoms. Condoms should be designed and produced in accordance with good quality management system ISO 14971 and ISO 1348.

e. Bidders should contact SABS to obtain a copy of the sampling frame guidelines prior to the submission of samples. All bidders must arrange random sampling in accordance with the SABS sampling frame guidelines at the point of packaging of the finished products. Sampling must be carried out by an independent or internationally recognised organisation. A list of approved agencies can be

obtained from SANAS. Samples must be taken from production lots produced at the source factory within the preceding 30 days from the date of sampling. Samples must be submitted to the SABS for batch testing which will be performed according to National Department of Health / World Health Organisation standards and specifications. All lot sizes for testing shall be between 144 000 and 288 000 pieces.

18. LABELLING

Labelling shall be performed in accordance with specification of products in Annexures A and B

19. CONTAINERS

The function of a container is to maintain the quality, safety and stability of its contents. The condition of container must be acceptable to purchaser at the point of delivery. The materials of construction should have no chemical or physical effect on the product. Containers should withstand the mechanical hazards of handling, transport and storage, prevent leakage and provide appropriate level of protection to the environmental conditions or contact with metal.

20. BARCODES

a. The packaging of all products supplied to the Department of Health must include a barcode (number plus symbology). Both the outer case and the specification pack must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as the standard. The batch number and the expiry date should be included in the barcode, if possible.

b. Bidders who are already in possession of the necessary block of numbers are requested to submit the EAN 13 numeric code(s) for each of the products offered as well as the outer case coding applicable to the distribution pack(s) (ITF 14) together with the quantity of items contained in such packs.

21. INSPECTIONS

a. The purchaser, as part of the purchase agreement and before delivery of the product, must approve any variance in the properties for compliance with specification requirements in Annexure A and Annexure B

b. Packaging will be tested for compliance by inspection. Inspections or verifications will generally be carried out at the pre-qualification stage, lot-by-lot compliance testing and during periodic inspections / audits.

22. QUALITY

Quality assurance requirements of condoms shall comply with those indicated in the products specification in Annexures A and B.

23. PERFORMANCE REQUIREMENTS

Performance requirements of condoms shall comply with those indicated in the products specification in Annexures A and B.

24. SHELF-LIFE

The shelf life requirements of condoms shall comply with those indicated in the products specification in Annexures A and B and shall be as follows:

- For male condoms it shall be five (5) years.
- For coloured male condoms it shall be five (3) years.
- For female condoms it shall be three (3) years.

A minimum of 80% of the shelf life of condoms shall be available to the purchaser at the time of delivery.

25. MANUFACTURING INFORMATION

a. Bidders must disclose the manufacturing site(s)

b. Any intention to change the condom manufacturing source prior to the commencement of the contract or during the lifetime of the contract must be approved by the Bid Adjudication Committee, National Department of Health.

26. PACKAGING

a. Packaging requirements of condoms shall comply with those indicated in the products specification in Annexures A and B.

b. 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.

c. Packaging requirements of condoms shall comply with those indicated in the products specification in Annexures A and B.

d. 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.

e. 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 packing 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

f. All products must be packed in acceptable containers, where applicable, specifically developed for the products.

27. POST AWARD PRODUCT COMPLIANCE PROCEDURES

Consignment/Batch Testing

a. All contractors must arrange random sampling (Sampling frame according to SABS guidelines) at the point of packaging of the finished products. Sampling must be carried out by an independent or internationally recognised organisation. A list of approved agencies can be obtained from SANAS. Samples must be taken from production lots produced at the source factory within the preceding 30 days from the date of sampling. Samples must be submitted to SABS for batch testing which will be done according to National Department of Health / World Health Organisation standards and specifications

The particulars for SANAS as in 17b above.

b. The contractors shall before the confirmation of orders and issue of delivery site quantities and delivery dates, provide the STI & HIV Aids Prevention unit of the Department of Health with compliance certificates proving adherence to the specification for each batch prior to shipment from the manufacturer.

c. Copies of these certificates must also accompany the proof of delivery documentation submitted for payment.

d. At the time of sampling the sampling agent will require certified documentation from the manufacturer indicating batch size of every batch sampled.

e. Sampling and testing organisations appointed by the Department of Health shall carry out all these certification tests.

f. The cost of these tests shall be borne by the Department of Health. The cost of tests in the event of failure of batches will be for the account of the contractor.

g. Test results are final and no requests for testing by other testing laboratories will be entertained by the Department of Health. Any performance failure (water, airburst, package seal integrity tests) will result in immediate and non-negotiable rejection of the batch.

h. Any cases of minor design failures will be treated on a case-by case basis taking into account the needs of the programme in relation to the particular failure. However, if an application for concession is made by a contractor and subsequently granted by the Department of Health, all testing costs for the concession batches will be borne by the contractor.

i. All lot sizes for testing shall be between 1000 and 2000 gross (i.e. between 144 000 and 288 000 pieces). All lot sizes must be certified at the time of sampling and this information must be communicated by the contractor to the Department of Health as soon as possible after certification. A lot is a single grade, class and composition manufactured under essentially the same conditions. All condoms comprising a lot will:

- Have an identical formulation.
- Have the same dimensions, shape, colour and texture
- Be manufactured on the same production line
- Be vulcanised under identical conditions
- Be manufactured within a period of 24 hours

- Not be made up of separate interrupted runs

j. With respect to the female condoms the supplier must submit complete documentation on the in-house manufacturing level, quality assurance programme in place at the point of manufacture. This will include descriptions of sampling and testing protocols, equipment in use including place of manufacture, date commissioned and calibration schedules and procedures. Original compliance test reports for every production batch (including tensile (cross-sectional seam), air inflation (measuring peak pressure) and water leakage tests), duly certified by senior management must be provided at the time of sampling.

28. COMPLIANCE TESTED STOCK LEVELS

a. Contractors will be required to have in-country, and immediately available for delivery, at least two month's compliance certified stock at the commencement date of the contract and this minimum stock level must be maintained through the end of quarter seven of the contract. (Stock level estimated from the anticipated requirements of the procurer and as indicated in the contract award unless otherwise instructed in writing by the procurer). This stock level requirement for compliant product may be adjusted by the Department of Health to respond to changing programmatic requirements.

b. Suppliers will be expected to deliver condoms according to delivery schedules issued periodically by the Department of Health against current compliant stock levels to any or all of 150-200 sites within the country. Delivery quantities shall generally range from 60 000 to 2000 000 condoms per male condom site and 5 000 to 60 000 condoms per female condom site. Once the delivery sites and quantities list is issued to suppliers, deliveries shall be made within ten working days. To the extent possible for male condoms, the procurer will serve sites utilizing stock available in the nearest proximity.

The supplier must inform delivery sites by phone at least 24 hours in advance as to when they should expect a delivery. Deliveries must be made within reasonable working hours, before 15:00 on week days. Delivery staff must ensure all cartons are stacked neatly, with all labels right side up, in the respective storage areas. It will be the supplier’s responsibility to ensure that adequate material offloading labour is provided. Delivery site staff is not obliged to assist with the materials offloading.

29. POST AWARD MONITORING

Any change in the status in supply performance during the contract period must be reported within seven (7) days of receipt of such information:

Pharmaceutical Policy and Planning, Affordable Medicines, Department of Health,
and

Cluster: HIV & Aids and STI's: Prevention Strategies for attention*:*

Sesupo Makakole-Nene (nenes@health.gov.za) Cluster: HIV & Aids and STI's: Prevention Strategies

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Cluster: HIV & Aids and STI's: Prevention Strategies

Tel. No: 012 395 9142

30. REPORTING AND HISTORICAL DATA

30.1 HISTORICAL DATA

Historical value and volume reports are required to be submitted monthly preferably via e-mail to the Department of Health for attention of Ms E Marumo (marume@health.gov.za), Ms B May (mayb@health.gov.za) and Ms M Mokgopo (mokgom@health.gov.za) by all successful bidders. For this purpose electronic templates which will include orders received and deliveries made will be supplied to successful bidders. The reports must be submitted on or before the 10th of each month.

31. PERFORMANCE MEASURES

31.1 SUPPLIERS MEASURES

a. Delivery period adherence

Product quality adherence

31.2 END USER MEASURES

On time payment

32. CONTACT DETAILS

Chief Directorate: Pharmaceutical Policy and Planning, Private Bag X828, Pretoria, 0001 or Physical address: 242 Struben Street, Civitas Building, Pretoria,0001.

Bid Enquiries:

Phuti Moloko Tel: (012) 395 8439 Fax: (012) 395 8823 Molokp@health.gov.za
Babalwa May: Tel: (012) 395-8442 Fax: (086) 632 9951 mayb@health.gov.za

Specification / Technical Enquiries :

Eva Marumo Tel: (012) 395-9142 Fax: (086) 632 8758 marume@health.gov.za

Sample Enquiries

Isabella Masemola South African Bureau of Standards Tel: 012 428 6131
e-mail: masemoig@sabs.co.za