health
Department:
Health
REPUBLICOFSOUTHAFRICA

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CONTACT: HP03-2013FP: SUPPLY AND DELIVERY OF FAMILY PLANNING AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 OCTOBER 2013 TO 30 SEPTEMBER 2015

1. The attached contract circular for your information.
2. This contract will be subject to the General Condition so if Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act,1999(Act1of1999). 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 of Contract will prevail.
3. The following provincial departments of Health will participate in this contract:

PARTICIPANTS	CONTACTPERSON	TELNO	FAXNO
EasternCape	A Morgan	(041)406-9821	086- 721-6201
FreeState	M Smits	(051)411-0544	(051)430-5344
Gauteng	D Malele	(011)628 -9001	(011)628-9130
KwaZulu-Natal	M Murran	(031)469-8324	(031)462-9737
Limpopo	S Rasekele	(015)223 -9000	(015)223 -9032
Mpumalanga	M Mashiane	(013)283 -9000	(013)283-9043
NorthWest	S Mokgatlha	(018)384-2977	(018) 384-3026
NorthernCape	L Roets	(053)830-2717	(053)832-3259
WesternCape	HHayes	(021)483-4567	(021)483-3886

HZEEMAN H Jzeeman
DIRECTOR:AFFORDABLE MEDICINES
For:DIRECTOR-GENERAL:HEALTH
DATE: 03-09-13

CONTACT: HP03-2013FP: SUPPLY AND DELIVERY OF FAMILY PLANNING AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 OCTOBER 2013 TO 30 SEPTEMBER 2015

1. IMPORTANT GENERAL INFORMATION:

1.1 Please note that the delivered price is for the unit of measure (UOM) offered.

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	**Supplier Code**	**Postal Address**	**Contact Person** **----------** **e-Mail Address**	**Telephone Number** **----------** **Fax Number**
Bayer (Pty) Ltd	V6390	P O Box 143 ISANDO 1600	Magda Noack/Wilma Swanich zabhcpricing@bayer.com	Tel: 011 921 5279/5842 Cell: 082 844 2380 Fax: 011 921 5272/ 086 639 6960
Fresenius Kabi South Africa Pty Ltd	VAJL3	P O Box 4156 HALFWAY HOUSE 1685	Albertha Nel albertha.nel@fresenius-kabi.com	Tel: 011 545 0000 Cell: 083 386 4000/083 386 4065 Fax: 011 545 0060
LithaPharma Pty Ltd	V2ZP5	P O Box 83 MIDRAND 1685	Martin Kahanovitz martin.kahanovitz@lithahealthcare.co.za	Tel: 011 516 7000/087 742 1684 Cell: 082 465 6055 Fax: 087 742 1660/1865
MSD Pty Ltd	V2185	Private Bag 3 HALFWAY HOUSE 1685	Fadila Rubidge fadiela.rubidge@merck.com	Tel: 011 655 3357/ 3139 Cell: 078 055 4767 Fax: 011 655 3429
Pharmacare Ltd	V2205	P O Box 4002 KORSTEN 6014	Ronny Boschmans ronnyb@aspenpharma.com	Tel: 041 407 2260 Cell: 082 781 8463 Fax: 041 409 3223
Triton Enterprises	V3432	P O Box 1982 BEDFORDVIEW 2008	Nicolas Cocolas manager@tritonent.co.za	Tel: 011 455 2639 Cell: 083 377 6016 Fax: 011 455 2625

CONTRACT NUMBER HP03-2013FP
SUPPLY AND DELIVERY OF FAMILY PLANNING AGENTS TO THE DEPARTMENT OF HEALTH
PERIOD: 1 OCTOBER 2013 TO 30 SEPTEMBER 2015

Item No	Description	Quantity Awarded	Name of Supplier	Supplier Code	Delivered Price	Brand Name	Unit Pack	Shipper Pack	Lead Time (Days)	Minimum order Quantity	Total Points	National Stock Number
1	Clip, tubal occlusion with mechanical locking device, X-ray detectable, sterile, supplied in pairs - 1 pair	4,500	Triton Enterprises	V3432	R 798.00	Filshie Clips (Femcare Nikomed)	1 Pair	1 Box (20 Pairs)	21	1 Box (20 Pairs)	93.00	18-183-4734(PR)
3	Intra-uterine system containing levonorgestrel 52 mg, releasing levonorgestrel 20 mcg/24 hours. Sterile, individually packed unit containing inserter, T-body with removal threads, in sealed sterilisation pouch.	1,000	Bayer (Pty) Ltd	V6390	R 1,300.00	Mirena	Each	230	14	1X1	90.00	18-035-9299(EA)
4	Injection containing medroxyprogesterone acetate 150 mg, 1 ml vial.	14,000,000	Fresenius Kabi South Africa (Pty) Ltd	VAJL3	R 5.9280	Petogen-Fresenius 150 mg/1 ml	Vial	20 x 100 vials	21	100	85.51	18-976-2873(VI)
5	Injection containing norethisterone enanthate 200 mg, 1 ml ampoule.	3,000,000	Bayer (Pty) Ltd	V6390	R 11.00	Nur-Isterate	Each (packed in 100s)	10	14	100 X 1ml	90.00	18-970-5261(AM)
6	Ring, fallopian tube, manufactured from dimethylpolysiloxane (silastic) containing two fallopian ring bands and one dilator. 50 pairs. Sterile, radio-opaque. One guide must be supplied for every two hundred pairs ordered.	100	Triton Enterprises	V3432	R 1,140.00	Sterile SMB Tubal Ring	1 Box (50 Pairs)	1 Box (50 Pairs)	21	1 Box (50 Pairs)	93.00	18-014-5945(BX) 18-971-4296(EA)
7	Monophasic, levonorgestrel 0.03mg tablet, 28 tablets in a blister pack	1,900,000	Pharmacare Ltd	V2205	R 2.3028	Microval Tabs	1 x 28	20x100x28	21	100 x 28	93.79	18-970-3093(CO)
9	Levonorgestrel 1.5 mg tablet, 1 tablet.	1,000,000	Litha Pharma Pty Ltd	VGS73	R 15.50	Escapelle	1	10	21	10	98.00	18-190-1862(EA)
10	Monophasic, 21 tablets each containing: levonorgestrel 0.15 mg and ethinyl oestradiol 0.03 mg plus 7 inert tablets. 28 tablets in a blister pack	4,500,000	Pharmacare Ltd	V2205	R 2.2230	Nordette Tabs	1 x 28	20x100x28	21	100 x 28	90.40	18-970-5223(CO)
12	Triphasic, 6 tablet each containing levonorgestrel 0.05 mg and ethinyl oestradiol 0.03 mg plus 5 tablets each containing: levonorgestrel 0.075 mg and ethinyl oestradiol 0.04 mg plus 10 tablets each containing: levonorgestrel 0.125 mg and ethinyl oestradiol 0.03 mg plus 7 inert tablets. 28 tablets in a blister pack	6,000,000	Pharmacare Ltd	V2205	R 2.2686	Triphasil Tabs	1 x 28	20x100x28	21	100 x 28	96.44	18-970-7391(CO)
13	Monophasic, 21 tablets each containing: norgestrel 0.5 mg and ethinyl oestradiol 0.05 mg plus 7 inert tablets. 28 tablets in a blister pack	1,900,000	Pharmacare Ltd	V2205	R 2.7132	Ovral Tabs	1 x 28	20x100x28	21	100 x 28	93.72	18-970-2739(CO)
14	Subdermal implant containing etonogestrel 68 mg + ready-for-use, disposable applicator (inserter). Sterile, radio-opaque, individually packed.	630,000	MSD Pty Ltd	V2185	R 91.62	Implanon nxt®	1 X 68mg		21	1	92.00	18-190-2532(CO)

Item No	Description	Quantity Awarded	Name of Supplier	Supplier Code	Delivered Price	Brand Name	Unit Pack	Shipper Pack	Lead Time (Days)	Minimum order Quantity	Total Points	National Stock Number
15	Subdermal implants containing levonorgestrel 75 mg per implant, 2 implants per ready-for-use, disposable applicator (inserter). Sterile, radio-opaque, individually packed.	70,000	Bayer (Pty) Ltd	V6390	R 101.74	Jadelle	1 x 10		14	1 x 10	90.00	18-190-2529 (CO)

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Special Requirements and Conditions of Contract

HP03-2013FP

SUPPLY AND DELIVERY OF FAMILY PLANNING AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 1 OCTOBER 2013 TO 30 SEPTEMBER 2015

VALIDITY PERIOD 120 DAYS

National Department of Health

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SPECIAL CONDITIONS OF ONTRACT

1. BACKGROUND

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 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)
- 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 parts of the bid 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 points for B-BBEE. Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.

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

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

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

2.2. DESIGNATION

a. In terms of regulation 9 of the Preferential Procurement Regulations pertaining to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), the Department of Trade and Industry has requested designation of Family Planning Agents included in this contract. to pharmaceutical manufacturers that formulate the medicine within South Africa. It is envisaged that 70% of these products (by volume) may be awarded to such local pharmaceutical manufacturers, hereinafter referred to as Local Manufacturers.

b. Preference will be given to 70% of volume to Local Manufacturers provided that bidders qualifying for preference regarding local content meet the following criteria:

- Adherence to all aspects stipulated in the Special Conditions of Contract; and
- Bids are within 10% of the highest points scored; and / or
- The provided that it is within range of the reference price according to list
- Demonstrated capacity to provide required quantity (by completing due diligence questionnaire PBD2)

c. Item awards and splits will be done in view of this designation for local preference

– See Section 15.

d. Local content must be declared on Form PBD3 and must be calculated on the **VAT-exclusive bid price.** This document must be signed by the Chief Executive Officer of the Bidder **per product** in order to be considered for local content.

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.

4.1. POST AWARD PARTICIPATION

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

The NDOH favours the participation of other departments, constitutional institution or public entity in this contract and intents to readily agree to requests to participate. The NDOH expects successful bidders to also respond favourably to such requests.

5. CONTRACT PERIOD

The contract period shall be for a period of 24 months commencing 1 October 2013 to 30 September 2015

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, bidders' attention is drawn to the response field and price structure explanations and examples supplied in the bid document.
t is mandatory that a completed signed hard copy of the document be submitted, which will be regarded as the valid bid. Bidders are also required to submit their bid response in the prescribed electronic format.

NOTE:

a. Failure to provide both the electronic in Excel format (not PDF) and hard copies may result in the bid not being considered.
b. Failure to complete all mandatory response fields for individual items may result in the bid not being considered.
c. It is mandatory that all bid documents be completed and signed, failure to comply may result in the bid not being considered.

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. It is obligatory that the validity of the Tax Clearance Certificate should be maintained throughout the duration of the contract.

Failure to comply with this condition may invalidate the bid.

9. AUTHORISATION DECLARATION AND LEGISLATIVE REQUIREMENTS

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 the bid at closing date and time of the bid. The Bid Authorization Form (Form PBD1) 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.

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 products offered.

g. Notwithstanding sections a to f above all accountability with regard to meeting the conditions of this contract rests with the bidder.

9.2. LEGISLATIVE REQUIREMENTS

a. The bidder offering medicines in terms of this bid must be licensed with the Medicines Control Council (MCC) in terms of section 22C (1) (b) of the Medicines and Related Substances Act, Act 101 of 1965, as amended, and must be the holder of the license according to section 22C (6) of the said Act. A certified copy of the licence including all annexure thereto must be submitted with the

bid document, at the closing date and time of bid.

b. Medicines offered by bidders must be registered in terms of section 15 of the Medicines and Related Substances Act, Act 101 of 1965 as amended, and bidders must indicate on the item response field the registration number of such an item in terms of the said Act. The medicines must comply with the conditions under which the medicine is registered at the closing date and time of bid. Certified copies of product registration certificates with the MCC should accompany the bid at closing date and time.

c. A copy of the MCC approved package insert for the product presented for bidding to accompany all bids.

d. All contracted suppliers must inform the Department within 7 days of notification by the MCC of an intention to withdraw a licence of manufacture or registration of an item on tender.

e. Non-compliance with the above mentioned legal requirements may invalidate the bid for such products offered.

10. CONTRACT ADMINISTRATION

a. Contracted suppliers must advise the Director: Affordable Medicines within 7 days of receiving an order when unforeseeable circumstances occur that may adversely affect supply against the contract. Full particulars of such circumstances must be provided.

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 the contact persons listed in Section 24.

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 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 contract by the bidder is discouraged.

f. Non-performance of contracted suppliers in terms of this contract may influence participation in future Department of Health contracts.

11. COUNTER CONDITIONS

Any amendments to any of the Bid Conditions or setting of counter conditions by the bidders may result in the invalidation of such bids.

12. PROHIBITION OF RESTRICTIVE PRACTICES

a. In terms of section 4 (1) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder(s) is / are or a contractor(s) was / were involved in:

   i. directly or indirectly fixing a purchase or selling price or any other trading condition;
   ii. dividing markets by allocating customers, suppliers, territories or specific types of goods or services; or
   iii. collusive bidding.

b. Section 4 (2) of Act No.89 of 1998 as amended states that an agreement to engage in a restrictive horizontal practice referred to in subsection (1)(b) of the Act is presumed to exist between two or more firms if:

   i. any one of those firms owns a significant interest in the other, or they have at least one director or substantial shareholder in common; and
   ii. any combination of those firms engages in that restrictive horizontal practice.

c. If a bidder(s) or contractor(s), in the judgment of the purchaser, has / have engaged in any of the restrictive practices referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.

d. If a bidder(s) or contractor(s) has / have been found guilty by the Competition Commission of any of the restrictive practices referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

13. 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 initiates 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.

14. PRODUCT COMPLIANCE

14.1. 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. Certified copy of product registration certificate with Medicines Control Council (MCC).

c. Compliance to Good Manufacturing Practice.

d. Valid relevant license from MCC.

e. Submission of samples of the products offered on this bid on or before the closing date and time of the bid at the address as provided in 14.2.

14.2. SAMPLES

a. No samples must not be sent to the Directorate: Affordable Medicines.

b. Samples must be submitted to each of the addresses indicated below, to be received before or at closing date and time of bid:

Ms S van Dyk Telephone: (011) 628 9003 Gauteng: Medical Supplies Depot – Store 3 35 Plunkett Avenue **Hurst Hill** 2092	Ms Helen Hayes Telephone: (021) 483 4567 Western Cape Department of Health Pharmaceutical Services 4 Dorp Street Room T14-02 **Cape Town** 8001

c. For accurate evaluation of samples, bidders must submit in original packaging at least one original pack of each offer.

d. Bidders must submit the following minimum quantities:

- Tablets – one original pack (x 2)
- Injectables – three ampoules or three vials
- Devices – one original pack
- Implants – one original pack

e. Only bids supported by samples will be considered and bidders must ensure receipt of samples at the venues listed in section (b) above.

f. Samples of each line item offered must be marked with the bid number, the item number as well as the bidder's name and address.

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

h. All samples must be submitted with an MCC approved package insert.

i. Samples of all products accepted against this bid will be retained for the duration of the contract period. These samples will be compared with product supplied during the contract period. Samples submitted by unsuccessful bidders must be collected by them within 3 months of the commencement of the contract. Samples not collected within the 3 month period will be destroyed.

j. Should samples not comply with specifications, package inserts or labels not meet legal requirements, such bids will not be considered.

15. AWARD CONDITIONS

a. The Department of Health will apply preference to Local Manufacturers. If local content of a product offered meets the criteria set out in paragraph 2.2 b, preference will be given to such bid(s).

b. The Department of health reserves the right to issue multiple awards in order to manage risks. The decision to issue multiple awards is based on estimated volume to be supplied, risk to public health if the item is not available and capability of bidder to supply the volume awarded. Where multiple awards are necessary domestic producers will be given preference based on the criteria below

c. Single award

- If there are no local manufacturers within 10% of the highest scoring bidder then 100 % of the volume may be awarded to the highest scoring bidder
- Where a local manufacturer scores within 10% of the highest points, then 100% volume may be awarded to the local manufacturer, irrespective of highest points scored

d. Split award (2)

- The local manufacturer with the highest points and within 10% of the bidder with the highest points may be awarded 70% of the volume. The bidder with the highest points may be awarded 30% of volume.
- Where there is no local manufacturer within 10% of the highest points then the volume distribution as described in table below will be applied.

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

e. The Department of Health reserves the right not to award a line item where the tender does not achieve the most economically advantageous price.

f. The following conditions will apply to all split awards:

- 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 API source and / or manufacturer.

g. The Department of Health reserves the right to change drug regimens and/or product formulations if necessary due to emerging clinical evidence, disease profiles, reported adverse drug reactions or resistant patterns.

16. PRICE QUALIFICATION

16.1. PRICING STRUCTURE AND CONTRACT PRICE ADJUSTMENT PROCEDURE

a. Prices submitted for this bid will be regarded as firm and only subject for review in terms of section 16.2.

b. Bidders must quote a final delivered price inclusive of Value Added Tax.

c. Bidders are advised to refer to the Reference Price List for Family Planning Medicines published on the Department of Health website (**www.doh.gov.za)** before preparing the bid submission.

d. Final price must include API price, formulation cost, packaging cost, transport cost, indicating the imported and local proportions of each component and value added Tax etc.

e. Bidders are referred to the pricing schedule in this regard.

16.2. PRICE REVIEW

a. The Department of Health envisages 2 types of price review processes for the duration of this contract:

- An adjustment to mitigate foreign exchange fluctuations
- A systematic review of prices for comparable products available publicly in the international marketplace.

b. Schedule for RoE Price Review :

Review	Average exchange rate for the period:	Submission of data for price review to reach the office by the following dates	Dates from which adjusted prices will become effective
1	1 March 2013 - 28 February 2014	7 March 2014	-1 April 2014
2	1 September 2013 - 31 August 2014	7 September 2014	1 October 2014
3	1 March 2014 - 28 February 2015	7 March 2015	1 April 2015

c. Contract price reviews based on average exchange rates as published by the Reserve Bank for the periods indicated above.

d. Only the imported cost component of the bid price will be adjusted taking into account the base RoE and the average RoE over the period under review

Currency	Rate of exchange Average for the period 1 November 2012 to 30 April 2013
Dollar	R8.91
Br Pound	R13.93
Euro	R11.68

e. Should the bidder make use of any currency not mentioned above, the bidder must stipulate this clearly and submit the calculated average RoE for the period 1 November 2012 to 30 April 2013 using the South African Reserve Bank published rates for the specific currency. Visit www.reservebank.co.za to obtain the relevant rates.

f. The review of the price adjustment for rate of exchange is applied from the base RoE.

g. Where rate of exchange has been not been applied for and it is in the in the favour of the Department this will be automatically applied.

h. Rate of Exchange increases may not result in a price exceeding the ruling Single Exit Price.

16.3. SYSTEMATIC REVIEW OF MARKETPLACE

The National Department of Health reserves the right to:

a. Perform a market review of the international pharmaceutical industry to ensure continued competitiveness of pricing.

b. Compare prices internationally with global most favoured nation pricing.

c. Should the review identify that contract prices are unfavourable; the Department of Health will contact and enter into price negotiations with the contracted supplier.

17. QUANTITIES, ORDERS AND DELIVERY

17.1. DELIVERY COMPLIANCE

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

b. Bidders must maintain regular supplies throughout the duration of the contract.

c. Bidders must adhere to delivery lead time (time from placement of order to delivery) as quoted in bid documents. This may not be longer than 3 weeks (**21 calendar days**).

d. The initial lead time as proposed in the bid response document will be calculated from date of award and **NOT** the first order. This may not exceed 60 calendar days from the date of award.

e. Bidders must make delivery of products in accordance with the instructions appearing on the official order forms emanating from Participating Authorities and institutions placing the orders.

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

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.

17.2. QUANTITIES AND ORDERS

a. The quantities reflected in the bid documents are estimated volumes for the basis of determining a bid price and as such cannot be guaranteed in terms of final award and procurement. During the award process and during the contract period, volumes may be varied according to:.

- Splitting award between suppliers
- Revision and implementation of Standard Treatment Guidelines
- Programmatic considerations

b. Monthly requirements will not be constant. The Department will meet with contracted suppliers quarterly to review supply performance and ongoing requirements.

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

e. Suppliers must under no circumstances deviate from orders issued by the departments.

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

g. The Department of Health reserves the right to purchase its requirements outside of the contract :

- If the contractor fails to perform
- If the item(s) are urgently required and not immediately available
- If minimum order quantity specified by the contractor exceeds an institution's requirements
- If an emergency arises

h. The Department of Health reserves the right to cancel orders where the lead time exceeds the delivery lead time as in the final contract.

17.3. MANUFACTURING INFORMATION

a. Bidders must disclose the manufacturing site(s) as well as the API supplier(s), as approved by the MCC.

b. Bidders must be able to substantiate the API price provided when requested.

c. Bidders must disclose future production plans which includes consideration of scale up and requirements for technical amendments with the MCC in order to service the bid volumes.

d. The Department reserves the right to conduct site visits to verify the production capacity.

e. Bidders must disclose their ability to maintain buffer stock within the country.

18. PACKAGING

a. Suppliers must ensure that supplies delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch as well as bulk storage according to Good Wholesaling Practice and Good Distribution Practice.

b. The number of "PACK" items in the commercial packing must appear on the bid documents. The packing must be uniform for the duration of the contract period, i.e.:

- The number of "PACK" items per commercial packing. The number of commercial packing per carton.

- The number of cartons per bulk packing.
- The name and quantity of the contents must appear clearly on the packing
- All containers, packing and cartons must be clearly labeled.
- All products must be packed in acceptable containers, where applicable, specifically developed for the product.

c. The following information must be clearly and indelibly printed on all inner and outer bulk packing in letters not less than 10mm in height:

- The proprietary name and quantity of the contents and expiry date if applicable must appear clearly on the packing.
- Date of manufacture.
- The number of commercial packing per carton. The number of cartons per bulk packing.
- The conditions under which the product must be stored.
- The name and quantity of the contents must appear clearly on the packing
- All containers, packing and cartons must be clearly labeled.
- All products must be packed in acceptable containers, where applicable, specifically developed for the product.

d. The following information must be clearly and indelibly printed on all inner and outer bulk packing in letters not less than 10mm in height:

- Product detail e.g. name, size, quantity etc.
- Date of manufacture.
- Batch number.
- Expiry date.

e. The Department of Health reserves the right to change drug regimens and/or product formulation if necessary due to emerging clinical evidence, disease profiles, reported adverse drug reactions and resistance patterns.

19. LABELS AND PACKAGE INSERTS

a. Labels and package inserts for medicines must comply with the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.

b. Where patient instruction labels form part of the package, bidders are advised to confirm requirements with the Department of Health.

20. CONTAINERS

The function of a container for a medical preparation is to maintain the quality, safety and stability of its contents. Containers should withstand the mechanical hazards of handling and transport, prevent leakage, and provide an appropriate level of protection from environmental conditions. Conditions of container must be acceptable to purchaser at the point of delivery. Ideally, the materials of construction should be sufficiently transparent to permit inspection of the contents whilst providing protection from incident radiation when necessary.

21. STERILITY

All injectable preparations are to be supplied sterile and apyrogenic.

22. BARCODES

a. It is a specific requirement that 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 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.

23. QUALITY

Products supplied in a consequence of this bid must conform in every aspect with the conditions of the registration lodged with Medicine Control Council.

24. SHELF-LIFE

a. Products, upon delivery, must have at least 18 months of shelf-life before date of expiry.

b. Contractors may make written applications to deliver material with a shorter shelf-life, provided that:

- Applications are accompanied by an undertaking that such short-dated stock will be unconditionally replaced before or after expiry
- That such applications are approved before execution of the orders.
- An undertaking is included that the following discount formula be applied for invoicing of short-dated stock:
  A=2 (18 – months to date of expiry) % X consignment value short dated stock. Therefore, amount to be invoiced is: Consignment value – A, where A is the discount formula.
- Any delivery of short dated supplies without prior written approval must be collected by the respective suppliers at their own cost. Failure to comply within 30 days after written advice, will result in the disposal of such supplies for the account of the supplier.

c. Any participating authority may, without prejudice, decline to accept stock with a shelf -life of less than 18 months.

25. POST AWARD

25.1. MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAIL

a. Where a contracted supplier merges with or is taken over by another, the contracted supplier must inform the Department of Health in writing 30 days prior to such event of relevant details.

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

c. A contracted supplier must inform the National Department of Health within 14 days of any changes of address, name or banking details.

25.2. THIRD PARTIES

a. Participating authorities will not make a payment to a third party.

b. No third party is entitled to put an account on hold.

25.3. MONITORING

The Department of Health will monitor the performance of contracted suppliers for compliance to the terms of this contract as follows:

a. Compliance to delivery lead times.

b. Percentage of orders not fully supplied first time (suppliers will not be penalised in this regard if they have been requested in time of shortages to supply part orders according to need)

c. Compliance with reporting schedule.

All suppliers of sub-dermal implant family planning delivery systems are to attend monthly suppliers meetings in accordance with the schedule as communicated by the Department of Health.

25.4. REPORTING

Suppliers must report monthly by the 7th day of the following month to the National Department of Health providing detail of orders received and products supplied in terms of this contract. The Department will provide contracted suppliers with the required format and content requirements of such reports. Reports should be submitted to the following e-mail address: medtenders@health.gov.za.

26. CONTACT DETAILS

Directorate: Affordable Medicines, Private Bag X828, Pretoria, 0001 or Physical address: 242 Struben Street Cnr Thabo Sehume Street, Civitas Building, Pretoria, 0001. Please use the following e-mail address to communicate with the Department: medtenders@health.gov.za

Ms Phuti Moloko:	Ms M Rasengane:	Mr R Kettledas:
Tel: (012) 395 8439	Tel: (012) 395 9452	Tel: (012) 395 9529
Fax: (012) 395 8823	Fax: (012) 395 8823	Fax: (012) 395 8823

27. ABBREVIATIONS

The abbreviations used in this bid signify the following:

B.P	=	British Pharmacopoeia (latest edition)
B.P.C	=	British Pharmaceutical Codex (latest edition)
GMP	=	Good Manufacturing Practice
g	=	gram
MCC	=	Medicines Control Council
mcg	=	microgram
mg	=	milligram
ml	=	milliliter
BEC	=	Bid Evaluation Committee
B-BBEE	=	Broad Based Black Economic Empowerment
NDoH	=	National Department of Health
SABS	=	South African Bureau of Standards
SBD	=	Standard Bidding Document
VAT	=	Value- Added Tax