health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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HP03-2015CHM: SUPPLY AND DELIVERY OF CONTRACEPTIVE AND HORMONE MODULATING AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 OCTOBER 2015 TO 30 SEPTEMBER 2017

1. The attached contract circular is for your information.
2. This contract will be subject to the General Conditions of Contract issued in accordance with Chapter 16A of the Treasury Regulations published in terms of the Public Finance Management Act,1999 (Act 1 of 1999). The Special Requirements and Conditions of Contract are supplementary to that of the General Conditions of Contract. Where, however, the Special Requirements and Conditions of Contract are in conflict with the General Conditions of the Contract, the Special Requirements and Conditions 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 PERSON	TEL NO	FAX NO
Eastern Cape	R Harris	(041) 408 9814	086 505 2871
Free State	M Smits	(051) 411 0544	(051) 430 5344
Gauteng	D Malele	(011) 628 9001	(011) 628 9130
Kwazulu-Natal	D Ogunsanwo	(033) 469 7269	(033) 469 7280
Limpopo	S Rasekele	(015) 223 9000	086 604 7766
Mpumalanga	B Thela	(013) 283 9002	(013) 283 9043
North West	S Mokgatlha	(018) 384 2977	(018) 384 3529
Northern Cape	H Bothma	(053) 830 2784	086 228 7074
Western Cape	N Mia	(021) 483 5800	(086) 6691294

K Jamaloodien

K JAMALOODIEN
DIRECTOR: AFFORDABLE MEDICINES
For: DIRECTOR-GENERAL: HEALTH
DATE: 28/8/2015

HP03-2015CHM: SUPPLY AND DELIVERY OF CONTRACEPTIVE AND HORMONE MODULATING AGENTS TO THE DEPARTMENT OF HEALTH FOR THE PERIOD 01 OCTOBER 2015 TO 30 SEPTEMBER 2017

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 Postal Address**	**Contact Detail ..... Telephone & Fax No.**	**Contact Person ..... E-mail Address**
Bayer (Pty) Ltd	V6390	PO Box 143 **Isando** 1600	(011) 921 5279 (011) 639 6960	Magda Noack zabhcpricing@bayer.com
Fresenius Kabi South Africa (Pty) Ltd	VAJL3	PO Box 4156 **Halfway House** 1685	(011) 450 0025 (011) 545 0060	Nadja Ferber Nadja.Ferber@Fresenius-Kabi.com
Litha Pharma (Pty) Ltd	VGS73	P O Box 83 **Midrand** 1685	(011) 742 1875 087 315 6220	Helen Pemberton helen.pemberton@lithahealthcare.co.za
MSD (Pty) Ltd	V2185	Private Bag 3 **Halfway House** 1685	(011) 655 3357 (011) 655 3429	Muriel Malape mmathuto.malape@merck.com
Mylan (Pty) Ltd	V3PS6	PostNet Suite # 23 Private bag X10010 **Edenvale** 1610	(011) 451 1300 (011) 451 1400	Nathi Mthethwa nathi.mthethwa@mylan.com
Pharmacare Limited	V2205	P O Box 1593 **Gallo Manor** 2052	(011) 239 6243 (011) 574 3175	Jaco de Wet jdewet@aspenpharma.com
Triton Enterprises	V3432	P O Box 1982 **Bedfordview** 2008	(011) 455 2639 (011) 455 2625	Ansie Brink ansie.brink@tritonent.co.za

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Item No	Item Specificaiton	Estimate	Quantity Awarded	% Split	Supplier Name	Supplier Code	Delivered price in ZAR	Registered Product Name	Pack Size Offered: Unit Pack	Lead-Time (days)	Minimum Order Quantity	Total score	National Stock Number	UOM
1	Intra-uterine contraceptive device (IUCD), device + inserter + explanatory booklet A flexible T-shaped, radio-opaque intra-uterine device with safe load and sound probe device Copper wire, producing 380mm² copper, to be wound around the stem, to which a monofilament thread is attached and around the transverse arms Device: approximately 32mm width; 36mm shaft length Wire diameter: 0,4mm **Sterile, individually packed.** **Must be registered with the MCC**		198 630		Bayer (Pty) Ltd	V6390	R 129.9000	Nova T 380	1 x 1	13	1 x 1	92.00	181795795	CO
3	Hystero meter (Probe) A graduated sounding instrument for measuring the depth of the uterine cavity. Device: approximately 27mm in length Straight, slightly conical and centimeter marked flange adjustable positioned to be set on the cervix external orifice Soft distal part on a rigid handle Diameter 3,3 mm Tip should be rounded to allow a comfortable insertion through the cervical canal Measurement scale ranges from 6 to 12 cm , must allow direct reading on the Hysterometer/Probe Single use, sterile , individually packed **To comply with the latest ISO13485** **Pack of 25**		7 945		Triton Enterprises cc	V3432	R 17.1000	SMB Hysterometer/ Probe	Each (1 unit)	14	1 Box (25 units)	98.00	181925737	EA
4	Monophasic, 21 tablets each containing: Levonorgestrel 0.15 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets **One unit of 28, blister packed tablets with a secondary outer package**	**4 826 954**	4 344 259	90%	Mylan (Pty) Ltd	V3PS6	R 2.0400	Oralcon	28	13	12	98.00	189705223	CO
			482 695	10%	Pharmacare Limited	V2205	R 3.1350	Nordette Tabs ***Spec deviation*** ***1 box (100 x 28's)***	28 Tablets	14	300 x 28	49.69		
6	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 **One unit of 28, blister packed tablets with a secondary outer package**	**6 174 489**	5 557 040	90%	Mylan (Pty) Ltd	V3PS6	R 2.2700	Trigestrel	28	13	12	98.00	189707391	CO
			617 449	10%	Pharmacare Limited	V2205	R 3.1578	Triphasil Tabs ***Spec deviation*** ***1 box (100 x 28's)***	28 Tablets	14	300 x 28	62.80		
11	Monophasic, 21 tablets each containing: Gestodene 0.075 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets **One unit of 28, blister packed tablets with a secondary outer package**		770 101		Bayer (Pty) Ltd	V6390	R 15.0000	Femodene ED	1 x 28	13	1 x 28	92.00	189762928	CO
13	Monophasic, LEVONORGESTREL 0.03mg tablet **28 tablets in a blister pack with a secondary outer package**		973 812		Mylan (Pty) Ltd	V3PS6	R 2.0900	HY-AN	28	13	12	98.00	189703093	CO
16	Levonorgestrel 1.5 mg tablet **1 tablet**		1 000 000		Litha Pharma (Pty) Ltd	VGS73	R 14.7500	Escapelle	1	14	10	94.00	181901862	EA
17	Monophasic, 21 tablets each containing: Norgestrel 0.5 mg and Ethinyl Oestradiol 0.05 mg plus 7 inert tablets **One unit of 28, blister packed tablets with a secondary outer package**		1 801 872		Mylan (Pty) Ltd	V3PS6	R 2.5700	Famynor	28	13	12	98.00	189702739	CO
18	Medroxyprogesterone acetate injection 150 mg **1 ml vial**		10 461 137		Fresenius Kabi South Africa (Pty) Ltd	VAJL3	R 5.5300	Petogen	1 unit	14	100 (1 x 100 units)	92.00	189710598	VI
19	Norethisterone enanthate 200 mg injection **1 ml ampoule**		7 557 588		Bayer (Pty) Ltd	V6390	R 11.0000	Nur-Isterate ***Spec deviation*** ***(Pack size 1 x 100)***	1 x 100	13	1 x 100	92.00	189750995	PK

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Item No	Item Specificaiton	Estimate	Quantity Awarded	% Split	Supplier Name	Supplier Code	Delivered price in ZAR	Registered Product Name	Pack Size Offered: Unit Pack	Lead-Time (days)	Minimum Order Quantity	Total score	National Stock Number	UOM
20	Clip, tubal occlusion with mechanical locking device, X-ray detectable sterile unit pack of **1 pair**		4 500		Triton Enterprises cc	V3432	R 855.0000	Femcare-Nikomed Filshieclips	Each (1 pair)	14	1 Box 20 pairs	98.00	181834734	PR
21	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 1 300.0000	Mirena	1 x 1	13	1 x 1	92.00	180359299	EA
22	Ring, fallopian tube, manufactured from dimethylpolysiloxane (silastic) containing two fallopian ring bands and one dilator. Sterile radio-opaque 50 pairs One guide must be supplied with every **50 pairs**		100		Triton Enterprises cc	V3432	R 22.8000	Sterile Smb Tubal Rings	Each (1 pair)	14	1 Box (50 pairs)	98.00	180145945	BX
23	Subdermal implant containing Etonogestrel 68 mg + ready-for-use, disposable applicator (inserter). Sterile, radiopaque, individually packed.		700 000		MSD (Pty) Ltd	V2185	R 115.3794	Implanon nxt®	1 x 68mg	13	10	92.00	181902529	CO

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Special Requirements and Conditions of Contract

HP03–2015CHM

THE SUPPLY AND DELIVERY OF CONTRACEPTIVES AND HORMONE MODULATING AGENTS TO THE DEPARTMENT OF HEALTH

FOR THE PERIOD 1 OCTOBER 2015 TO 30 SEPTEMBER 2017

VALIDITY PERIOD: 120 days

National Department of Health

Compulsory Briefing Session
24 March 2015
Time: 10:00-12:00
Venue:
National Department of Health
Civitas Building, Impilo Board Room, North Tower, Podium Level
242 Struben Street (Cnr Thabo Sehume and Struben streets), Pretoria

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SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT

1. BACKGROUND

This bidding process, 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 Requirements and Conditions of Contract are supplementary to the General Conditions of Contract. Where 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

2.1.1. In terms of Regulation 6 of the Preferential Procurement Regulations, published in terms of the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive bids will be adjudicated by the Department of Health on the basis of the 90/10- preference point system in terms of which points are awarded to bidders on the basis of:

- The bid price (final delivered price including VAT): maximum 90 points
- B-BBEE status level of bidder: maximum 10 points

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

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

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

2.1.3. A maximum of 10 points may be allocated to a bidder for attaining their B-BBEE status 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) irrespective of whether B-BBEE status level points are claimed or not.

2.1.5. The points scored by a bidder for 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 preference claim form, and who have submitted a B-BBEE status level certificate issued by a registered auditor, accounting officer (as contemplated in section 60(4) of Close Corporation Act, 1984 (Act 69 of 1984)) or an accredited verification agency will be considered for preference points.

2.1.7. Bidders that fail to comply with paragraphs 2.1.4 and 2.1.6 will be allocated zero points for B-BBEE status.

2.1.8. 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 points.

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

2.1.10. 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.

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

3. PRE AWARD SUPPLIER DUE DILIGENCE

The Department of Health reserves the right to conduct supplier due diligence prior to the final award of contract. Supplier capacity will be assessed based on past performance for items, declared manufacturing capacity and financial resources.

4. PARTICIPATING AUTHORITIES

The National Department of Health and the following Provincial Departments of Health will participate in this contract: Eastern Cape, Free State, Gauteng, KwaZulu-Natal, Limpopo, Mpumalanga, Northern Cape, North West and Western Cape.

4.1. POST AWARD PARTICIPATION

Regulation 16A6.6 of the Treasury Regulations for Departments, Trading Entities, Constitutional Entities and Public Entities, issued in terms of the Public Finance Management Act, 1999, (Act 1 of 1999), states that the Accounting Officer/Accounting Authority may, on behalf of a department, constitutional institution or public entity, request to participate in any contract arranged by means of a competitive bidding process by any organ of state, subject to the written approval of such organ of state and the relevant contractors.

5. CONTRACT PERIOD

The contract period shall be for a period of 36 months commencing on 1 October 2015.

6. DOCUMENT SUBMISSION AND COMPLETION FOR BIDDING

6.1. BID DOCUMENTS FOR SUBMISSION

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

- SBD1: Invitation to bid
- SBD2: Tax Clearance Certificate: Certificate must be original and valid
- SBD4: Declaration of Interest
- SBD5: The National Industrial Participation Programme

- SBD6.1: Preference points claim form in terms of the Preferential Procurement Regulations 2011
- SBD8: Declaration of bidder's past supply chain management practices
- SBD9: Certificate of independent bid determination
- PBD1: Authorisation Declaration (if applicable)
- PBD4: Supplier details
- PBD5: Declaration of compliance with Good Manufacturing Practice (GMP)
- PBD7: Compulsory briefing session attendance certificate
- Bid Response Documents: Completion of all response fields per item offered is mandatory.
- B-BBEE Status Level Verification Certificate (if applicable) (Original or Certified Copy)
- Certified document of the CIPC document (Reflecting the Entity's Registration Number and Registered Name)
- A certified copy of the License to Manufacture issued by the Medicine Regulatory Authority with **all annexures**.
- Copy of final MCC approved package insert (A4) per product offered (Note: this is not to be confused with the submission of samples).
- Certified copy of certificate of Medicine Registration Certificate (GW12/7) **with all annexures** issued by the Regulator for all items. If the certificate is not yet issued at the close of the bidding process, the available data elements must be furnished on Form 1.

  Note that item 3 does not require registration with the Medicine Regulatory Authority.

6.2. COMPLETION OF DOCUMENTS AND BID SUBMISSION

Bidders are required to submit three sets of bid documents according to the instructions below. All three sets must be submitted before the closing date and time. Set 2 and Set 3 must be included on a CD with Set 1 and submitted in **a sealed** package. The full name and address of the bidder, including the return address, the bid number and the closing date must be clearly indicated on the package. All fields must be completed. Where information requested is not relevant this should be indicated with N/A.

6.2.1. Set 1: Hard copy legally binding bid documents

Bidders must complete all SBD, PBD and Bid Response forms in black ink, **typed**. Where no electronic entry field is provided bidders must complete the forms in

black ink, handwritten in capital letters. The signed hard copy of the bid document will serve as the legal bid document. Bidders must submit their complete bid in hard copy format (paper document). The Chief Executive Officer, Chief Financial Officer, or authorised designee of the entity submitting the bid must sign the official signature pages. All pages in the complete bid document must be initialled by same with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled.

6.2.2. Set 2: PDF of Hard Copy, signed legal documents. (i.e. pdf of Set 1)

Bidders **must** submit a PDF version of the entire signed hardcopy bid, including all certificates and documents requested.

6.2.3. Set 3: Electronic version of bid documents

Bidders must submit the electronic versions (editable pdf) of all SBD and PBD documents and Bid Response Document in Excel (not pdf).

6.2.4. All three sets of information must be submitted in order for the bid to be evaluated.

6.2.5. Ensure that the bid price is offered for the product as specified.

7. VALUE ADDED TAX

All bid prices must include Value-Added Tax (VAT). If a VAT exclusive price is submitted the bid will be deemed non-responsive.

8. TAX CLEARANCE CERTIFICATE

An original and valid Tax Clearance Certificate issued by the South African Revenue Service must be submitted together with bid documents. Only the original Tax Clearance Certificate will be accepted. Contracted Suppliers are obliged to provide the Department with a valid Tax Clearance Certificate prior to the expiry of the previously submitted certificate.

9. LEGISLATIVE REQUIREMENTS AND AUTHORISATION DECLARATION

9.1. LEGISLATIVE REQUIREMENTS

9.1.1. All medicines offered by bidders must be registered in terms of section 15(7) of the Medicines and Related Substances Act, Act 101 of 1965, as amended. The medicines must comply with the conditions of registration for the duration of the contract.

9.1.2. The bidder must hold, and be represented as the applicant, on the Medicine Registration Certificate GW12/7, for all offered products, in terms of section 15(3)(a) of the Medicines and Related Substances Act, Act 101 of 1965.

9.1.3. The bidder offering a product must be the holder of a License to Manufacture Medicines in terms of section 22C(1)(b) of the Medicines and Related Substances Act, Act 101 of 1965, as amended.

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

9.1.5. Bidders should comply with the requirements of the Patents Act, 1978 (Act 57 of 1978) and the Trade Marks Act, 1993 (Act 194 of 1993) as amended. Where applicable, an explanation for non-compliance must be provided.

9.2. DECLARATION OF AUTHORISATION

9.2.1. Only the holder of a certificate of registration in terms of the Medicines and Related Substances Act, Act 101 of 1965, may submit a bid.

9.2.2. In the event that the Manufacturer, Packer or other, as listed on the medicine registration certificate, are external, third parties the bidder must ensure that all legal, financial and supply arrangements have been mutually agreed upon between the bidder and these third parties, e.g. third-party importers, contract manufacturer etc.

9.2.3. No agreement between the bidder and a third party will be binding on the Department of Health.

9.2.4. Where third-parties are involved the bidder must submit a duly completed and signed Authorisation Declaration (PBD1). Failure to submit the full declaration will invalidate the bid for such goods offered.

9.2.5. The Department reserves the right to verify any information supplied by the bidder in the Authorisation Declaration at any time. Should the information be found to be false or incorrect, the Department of Health will exercise any of the remedies available to it in order to disqualify the bid, or cancel the contract, if already awarded.

9.2.6. Accountability with regard to meeting the conditions of any contract emanating from this bidding process rests with the successful bidder and not any third party.

10. BIDDING PROCESS ADMINISTRATION

10.1. The Affordable Medicines Directorate within the National Department of Health is responsible for managing the bidding process and will communicate with bidders to request extension of the validity period of the bid, should it be necessary.

10.2. All communication between the bidder and the Department of Health must be in writing and addressed to the Director: Affordable Medicines.

10.3. Any unsolicited communication between the closing date and the award of the contract between the bidder and any government official or a person acting in an advisory capacity for the Department of Health in respect to any bids, is discouraged.

11. COUNTER CONDITIONS

Any amendments to any of the bid conditions, changes to bid specifications or setting of any other counter conditions by bidders will result in the invalidation of such bids.

12. PROHIBITION OF RESTRICTIVE PRACTICES

12.1 In terms of section 4(1) of the Competition Act, Act 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:

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

12.2 Section 4(2) of Act 89 of 1998 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:

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

12.3 If bidder(s) or contracted supplier(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 89 of 1998.

12.4 If bidder(s) or contracted supplier(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 contracted supplier(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 contracted supplier(s) concerned.

13. FRONTING

13.1 The Department of Health supports the spirit of broad-based black economic empowerment and recognises that real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background the Department of Health condemns any form of fronting.

13.2 The 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 Treasury may have against the bidder/contractor concerned.

14. PRODUCT COMPLIANCE

Prior to award products will be evaluated for:

- Compliance with specifications as set out in the Bid Response Document.
- Product registration with Medicines Control Council. Note that item 3 does not require registration with the Medicine Regulatory Authority. However, proof of compliance with the ISO standard must be submitted.
- Availability of sample and physical compliance of both samples with the specification.

14.1. SUBMISSION OF SAMPLES

14.1.1. No samples must be sent to the Directorate: Affordable Medicines.

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

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

14.1.4. Bids where samples are not submitted to both facilities listed in section 14.1.5, will not be considered for award.

14.1.5. Samples must be submitted to each of the addresses indicated below, prior to closing date and time of bid:

Mr Dumisani Malele	Mr Nisaar Mia
Depot Manager	Pharmaceutical Policy Specialist
Tel: 011 628 9001	Tel: 021 483 5800
Gauteng: Medical Supplies Depot	Western Cape: Department of Health
Store 3	Pharmaceutical Services
35 Plunkett Avenue	4 Dorp Street Room 10-07
Hurst Hill	Cape Town
2092	8001

14.1.6. It is the responsibility of the bidder to ensure that samples have been received at the addresses provided.

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

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

14.1.9. All samples submitted must be inclusive of the MCC approved package insert.

15. PRODUCT AWARD

15.1. AWARD CONDITIONS

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

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

15.1.3. In cases where the tender does not achieve the most economically advantageous price, the Department of Health reserves the right not to award that item.

15.1.4. The Department of Health requires pack sizes suitable for a 28 day treatment cycle. Should a 30-day pack size be offered, no conversion factor will be applied. Direct comparisons will be made between 28 and 30 day pack sizes.

15.1.5. The Department of Health reserves the right to change treatment protocols and/or product formulations where required due to emerging clinical evidence, disease profiles, safety or resistance patterns.

15.2. SPLIT AND MULTIPLE AWARDS

15.2.1. The Department of Health reserves the right to issue split or multiple awards, where necessary, to ensure security of supply.

15.2.2. The following will be taken into consideration when contemplating a split award:

- Source of API and manufacturing site.
- Capacity to meet volume demand as per Bid Response Document.
- Estimated volume to be supplied.
- Risk to public health if the item is not available.
- Previous performance of the bidder.

15.2.3. Two-way split awards will be made in accordance with the following schedule based on the points scored:

Category	Difference between points scored	Recommended percentage split
A	Equal points	50/50
B	< 5 points	60/40
C	>5-10 points	70/30
D	>10-20 points	80/20
E	>20 points	90/10

15.2.4. Where a split for more than 2 suppliers is contemplated, the following formula will used to allocate volumes for award:

- For a three way split: Supplier share = 33.3% + (supplier score - mean score) x 2.3%
- For a four way split: Supplier share = 25% + (supplier score - mean score) x 2%

16. THERAPEUTIC CLASSES

16.1. GENERAL INFORMATION

16.1.1. To achieve the most economically advantageous contract in the case of specific items, the Department of Health invites bids based on the classes and/or group(s) as listed in section 16.1.5 below.

16.1.2. A Single member of the class will be awarded.

16.1.3. Classes are listed below:

Class 1: Low dose monophasic , first line

- Monophasic, 21 tablets each containing: Levonorgestrel 0.15 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package.
- Monophasic, 21 tablets each containing: Levonorgestrel 0.05 mg and Ethinyl oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package

Class 2: Triphasic

- 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. One unit of 28, blister packed tablets with a secondary outer package.
- Triphasic, 6 tablet each containing Gestodene 0.05 mg and Ethinyl Oestradiol 0.03 mg plus 5 tablets each containing: Gestodene 0.070 mg and Ethinyl Oestradiol 0.04 mg plus 10 tablets each containing: Gestodene 0.10 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package
- Triphasic, 7 tablets each containing Norethisterone 0.5 mg and Ethinyl Oestradiol 0.035 mg plus 7 tablets each containing: Norethisterone 0.75 mg and Ethinyl oestradiol 0.035 mg plus 7 tablets each containing: Norethisterone 1 mg and Ethinyl Oestradiol 0.035 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package.

Class 3: Low Dose Monophasic, second line

- Monophasic, 21 tablets each containing: Drospirenone 3 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package
- Monophasic, 21 tablets each containing: Gestodene 0.075 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package
- Monophasic, 21 tablets each containing: Desogestrel 0.15 mg and Ethinyl Oestradiol 0.03 mg plus 7 inert tablets. One unit of 28, blister packed tablets with a secondary outer package

Class 4: Progesterone only

- Monophasic, **levonorgestrel** 0.03mg tablet. One unit of 28, blister packed tablets with a secondary outer package.
- Monophasic, **norethisterone** 0.35 mg tablet, One unit of 28, blister packed tablets with a secondary outer package

Class 5: Emergency Contraceptive

- Levonorgestrel 0.75 mg tablet, 2 tablets
- Levonorgestrel 1.5 mg tablet, 1 tablet

Class 6: Subdermal implant

- Subdermal implant containing Etonogestrel 68 mg + ready-for-use, disposable applicator (inserter). Sterile, radio-opaque, individually packed.
- Subdermal implants containing Levonorgestrel 75 mg per implant, 2 implants per ready-for-use, disposable applicator (inserter). Sterile, radio-opaque, individually packed.

17. PRICE QUALIFICATION

17.1.1. Prices submitted for this bid will be regarded as firm and subject only to review in terms of Section 18.

17.1.2. Bidders must quote a final delivered price inclusive of Value Added Tax (VAT) and delivery.

17.1.3. Price must be specific for the units advertised per item specification.

17.1.4. Bidders are advised to refer to the Reference Price List for HP03-2015CHM as published on the Department of Health website (www.health.gov.za) before preparing the bid submission

18. PRICE REVIEW

The Department of Health envisages two 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 in the international marketplace.

18.1. INSTRUCTIONS FOR PRICE BREAKDOWN

18.1.1. The price breakdown must be completed on the signed bid response document. The delivered price must be divided across five components:

1. Active Pharmaceutical Ingredients (API);
2. Formulation;
3. Packaging;
4. Logistics;
5. Gross margin (remaining portion).

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

18.1.3. The local + imported portions of the first three components must add up to 100% within each component (e.g. Portion of API attributable to local + Portion of API attributable to import = 100% of specific API component).

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

18.1.5. Labour must be apportioned appropriately across the relevant components.

18.1.6. Breakdown must be in percentage format to the closest whole percentage (e.g. 20%). No decimals will be considered.

18.1.7. The Department of Health reserves the right to engage with bidders to verify the any of the components of the bid price, which may include audit of invoices and related documentation.

18.2. PRICE ADJUSTMENTS RELATING TO FOREIGN EXCHANGE RISK

18.2.1. Only the portion of the bid price facing foreign exchange risk will be adjusted. This portion is determined by the price breakdown on the signed bid submission

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

18.2.3. Price adjustments relating to foreign exchange will be based on the percentage change between a base average rate of exchange (RoE) and an adjustment average RoE. Rates are sourced from the Reserve Bank (www.resbank.co.za).

18.2.4. The Department of Health reserves the right to engage with bidders to verify the any of the components of the bid price, which may include audit of invoices and related documentation.

18.2.5. Eligibility for favourable Contractual Price Adjustments may be withdrawn in light of evidence of poor supplier performance.

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

Currency	Base Average Rates of Exchange Average for the period 1 September 2014 to 28 February 2015
Rand per US Dollar	11.2831
Rand per Br Pound	17.7297
Rand per Euro	13.8022
Yuan Renminbi per Rand	0.5475
Indian Rupee per Rand	5.4771

18.2.7. 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 September 2014 – 28 February 2015 using the South African Reserve Bank published rates for the specific currency.

18.2.8. Schedule for price reviews, and periods for calculating adjustment average RoE, are detailed in the table below:

Review	Period for calculating adjustment RoE	Submission of request for price review to reach the office by	Date from which adjusted prices will become effective
1	1 Sept 2014 – 28 Feb 2015	1 March 2016	1 April 2016
2	1 March 2016 – 31 Aug 2016	1 Sept 2016	1 October 2016
3	1 Sept 2016 – 28 Feb 2017	1 March 2017	1 April 2017

18.2.9. Signed applications for price adjustments must be received by the National Department of Health prior to the submission dates detailed in the table above. Successful bidders will receive the price adjustment request template when signing their contracts.

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

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

18.3. PRICE ADJUSTMENTS BASED ON A SYSTEMATIC REVIEW

18.3.1. The National Department of Health reserves the right to review international prices to identify lowest comparable global prices

18.3.2. Where this review identifies any prices that are lower than contract prices the Department of Health will enter into price negotiations with the contracted supplier.

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

19. ORDERS, DELIVERY AND CONTINUITY OF SUPPLY

19.1. ORDERS

19.1.1. The quantities reflected in the advertised bid response document are estimated volumes and are not guaranteed.

19.1.2. Fluctuations in monthly demand may occur.

19.1.3. Proposed minimum order quantities should facilitate delivery directly to facilities. The Department reserves the right to negotiate minimum order quantities where they are deemed unfavourable. Where consensus regarding minimum order quantities cannot be reached the bid may not be awarded.

19.1.4. In order to facilitate efficient implementation of the direct delivery strategy contracted suppliers must pack orders by facility-specific purchase orders to support cross-docking.

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

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

19.1.7. The Participating Authorities reserve the right to cancel orders where the lead time exceeds the delivery lead time specified in the contract (as per section 19.2 of the Special Requirements and Conditions of Contract).

19.1.8. In cases where an order is received which appears to be irrational or misaligned with estimates, the contracted supplier must liaise with the relevant Participating Authority prior to processing the order.

19.2. DELIVERIES

19.2.1. The initial lead time as proposed in the bid response document will be calculated from date of award of the contract and NOT the date of placement of the first order. This period may not exceed 75 calendar days from the date of award.

19.2.2. Lead-time within the contract period is defined as the time from submission of order to supplier to time of receipt by the department as confirmed by the Proof of Delivery document. This lead-time may not exceed 14 calendar days.

19.2.3. Failure to comply with the contractual lead-time will result in penalties being enforced as per section 21 and 22 of the General Conditions of Contract.

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

19.2.5. The information on invoices and documents relating to delivery must comply with the minimum data requirements as defined by the National Department of Health. These requirements will be communicated upon signing of the contract .

19.2.6. Original invoices and proof of delivery must be authorised by a delegated official at the designated delivery point. These documents must be delivered to the authority responsible for payment.

19.2.7. The supplier must ensure that products are delivered in accordance with the appropriate conditions of storage, as per product's conditions of registration. Delivery is deemed to terminate upon signature of receipt by the delegated official as contemplated in paragraph 19.2.6.

19.2.8. Discrepancies between invoice and physical stock, or damaged stock, will be reported to the contracted supplier within a reasonable time or as arranged with the supplier. This time period must make provision for the quantities received to be checked upon receipt of delivery.

19.2.9. Contracted suppliers will be responsible for collection of goods delivered erroneously, or in the incorrect condition as formally arranged in consultation with the facility. The Department of Health reserves the right to recuperate any expenses associated with failure to collect in accordance with the agreement.

19.3. CONTINUITY OF SUPPLY

19.3.1. Contracted suppliers must:

- maintain sufficient stock to meet demand throughout the duration of the contract;
- inform the National Department of Health at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
    1. regulatory action which may impact on their GMP status or those of regulated entities that they are reliant on;
    2. any anticipated problems associated with the availability of active pharmaceutical ingredient (API)
    3. industrial action,
    4. manufacturing pipeline
    5. any other supply challenges.
- direct official communication relating to continuity of supply to stockalert@health.gov.za, as well as Participating Authorities;
- this official communication must include detail of corrective actions taken by contracted supplier to ensure continuity of supply.

19.3.2. In terms of the General Conditions of Contract and Special Requirements and Conditions of Contract, the Department of Health reserves the right to purchase outside of the contract in order to meet its requirements if :

- the contracted supplier fails to perform in terms of the contract;
- the item(s) are urgently required and not immediately available;
- in the case of an emergency.

20. PACKAGING AND LABELLING

20.1. PACKAGING

20.1.1. Suppliers must ensure that products delivered are received in good order at the point of delivery. Packaging must be suitable for further dispatch, storage and stacking according to Good Wholesaling Practice and Good Distribution Practice.

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

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

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

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

20.1.6. Where the contents of the shipper pack represents a standard supply quantity of an item, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering
- The contents must be packed in neat, uniform rows and columns that will facilitate easy counting when opened.

20.1.7. Where the contents of a shipper pack represents a non-standard supply quantity, the following must be adhered to:

- Outer packaging flanges must be sealed with suitable tape that will clearly display evidence of tampering.
- The shipper pack must contain only one product, mixing of multiple items in a single shipper is not allowed.
- The outer packaging must be clearly marked as a "Part Box".

20.2. LABELLING

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

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

- Generic name and strength
- Proprietary name (if applicable)
- Number of units in pack (e.g. for bulk packs 80 x 10 x 100s)
- Batch number
- Expiry date
- Storage conditions
- Barcode

20.2.2. Where the contents of the shipper requires special attention in terms of storage or handling, e.g. thermolabile, high-scheduled or cytotoxic products, such instructions must be clearly and visibly indicated on the outer packaging on a brightly coloured background.

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

20.3. BARCODES

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

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

- The generic name of the product
- Brand name
- Dosage form and strength
- Pack size
- Batch number
- Expiry date

21. QUALITY

Products must conform with the conditions of registration of the product with Medicines Control Council for the full duration of this contract.

22. SHELF-LIFE

21.1 Unless the stability of a product has required the MCC to approve a shorter shelf life, products must have a shelf-life of at least 18 months upon delivery.

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

- Applications are accompanied by an undertaking that such short-dated products will be unconditionally replaced or credited before or after expiry; **and**
- applications are approved before execution of orders; **and**
- such products must be collected by the supplier at their own cost; **and**
- failure to collect the products within 30 days after written notification to the supplier will result in the disposal of the product by the Participating Authority for the account of the supplier.

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

A = (18 – months to date of expiry) x 2% x consignment value short dated product. Therefore, amount to be invoiced is: Consignment value minus A, where A is the value of the outcome of the discount formula.

21.4 Any Participating Authority may, without prejudice, decline to accept product with a shelf-life of less than 18 months.

23. POST AWARD

23.1. REGISTRATION ON DATABASES OF PARTICIPATING AUTHORITIES

23.1.1. All contracted suppliers must register on the supplier databases of Participating Authorities within 30 days after award of contract.

Failure to meet this requirement will result in inability to process payment for goods.

23.2. MONITORING

23.2.1. The management of the contract is the responsibility of the National Department of Health. All correspondence in this regard must be directed to the Director: Affordable Medicines.

23.2.2. Contracted suppliers must advise the Director: Affordable Medicines at first knowledge of any unforeseeable circumstances that may adversely affect supply against the contract. Full particulars of such circumstances must be provided by the supplier as contemplated in section 18.3.

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

- Compliance to delivery lead times;
- Percentage of orders supplied in full first time;
- Compliance with reporting requirements according to reporting schedule.
- Attendance of compulsory quarterly meetings: The National Department of Health will hold quarterly meetings with suppliers to review the next quarter's demand, as well as supplier performance.

23.2.4. The National Department of Health will request Participating Authorities to impose penalties, where deemed necessary, as per Section 21 and 22 of the General Conditions of Contract.

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

23.3. REPORTING

23.4. National Department of Health will provide successful bidders with the compulsory templates and schedule for reporting.

23.5. MERGERS, TAKE OVERS AND CHANGES IN SUPPLIER DETAILS

23.5.1. Where a contracted supplier plans to merge with or is going to be acquired by another entity, the contracted supplier must inform the Department of Health in writing 30 days prior to such event of relevant details.

23.5.2. 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.

23.5.3. A contracted supplier must inform the National Department of Health within 5 days of any changes of address, name, contact or banking details.

23.6. THIRD PARTIES

23.6.1. Participating authorities will not make a payment to or consult with a third party.

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

23.7. CONTACT DETAILS

Postal address	Physical address
Director: Affordable Medicines, Private Bag X828, Pretoria, 0001	Director: Affordable Medicines, Civitas Building, 242 Struben Street, Cnr Thabo Sehume Street, Pretoria, 0001

Please use the following e-mail address and contact persons for any queries relating to bidding process:

Ms P Moloko	Ms M Rasengane
Tel: (012) 395 8439	Tel: (012) 395 9452
Fax number: (012) 395 8823	
Email: medtenders@health.gov.za	

24. ABBREVIATIONS

The abbreviations used in this document signify the following:

API	Active Pharmaceutical Ingredient
B-BBEE	Broad-Based Black Economic Empowerment
BEC	Bid Evaluation Committee
GMP	Good Manufacturing Practice
MCC	Medicines Control Council
NDoH	National Department of Health
RoE	Rate of Exchange
VAT	Value Added Tax