

TENDER NO. : DHS/SUS/86/F/2012
DATE OF ISSUE : 24TH MAY 2012
CLOSING DATE & TIME : 10TH JULY 2012 AT 0930 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the Cosmetic Devices and Drugs Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number.
3. However at the tender opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
4. **Offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. Total value of each item not exceeding LKR 1 Million for Import and Supply basis is acceptable. Offers exceeds this amount should be on C & F basis. This is not applicable for local manufacturers.**
5. **Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.**
6. If awarded supplier is unable to adhere the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
7. We reserve the right to reject offers which do not comply above.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected

General Conditions apply in the event of an award :

1. To be supplied from freshly manufactured stock and should reach Medical Supplies Division within 3 months of manufacture.
2. **The product should have minimum of 24 months shelf life** at the time of delivery at Medical Supplies Division.
3. The product should be stable under normal room temperature (30°C- 35°C) and humidity (75%-100%) prevailing in Sri Lanka.
4. **Pre-qualifications:**

The manufacturer should have the following documents

1. Good Manufacturing Practices (GMP) certification in accordance with recommendations of WHO, from the country of manufacture.
2. Evidence of pre-qualification by International organizations (E.g. UNFPA, WHO, USAID, Population Council, IPPF etc)
3. Registration in Sri Lanka
4. Certificate of the pharmaceutical product (COPP)
5. Registration for product to be marketed in the country of manufacture.
6. Evidence of use in the country of manufacture.
7. Periodic safety update reports for the past 1 year
8. Real time stability data at recommended storage conditions (30-35)°C for 5 years.
9. A certificate of analysis from a WHO accredited laboratory for all batches prior to shipment, on the onus of the supplier. The test result should conform to the specifications declared by the manufacturer.

N.B. Even after delivery of goods, samples of the product will be sent to a WHO accredited laboratory at the supplier's expense if there is any suspicion of quality failure or complaint regarding the product.

Labelling:

Implant and Disposable Trocar should be labeled separately and contain the following information:

Blister pack:

8. Date of manufacture, date of expiry and batch/lot No.
9. The logo of the Family Health Bureau, logo of Government of Sri Lanka and the Letters **FHB** should be clearly printed in black.
10. The wording "NOT FOR SALE" should be printed in red on the vial.

Inner Box:

- Date of manufacture, Date of expiry and batch /lot No.
- The logo of the Family Health Bureau, Logo of Government of Sri Lanka
- The wordings Family Health Bureau, Ministry of Health, Sri Lanka should be clearly printed in black.
- Storage condition, Name of manufacturer, Country of origin.
- The wording "NOT FOR SALE" should be printed in red.

Outer (Corrugated) Box:

A Label should be pasted or printed on all four sides of the box with the following information.

11. Generic name and strength (also Brand name if applicable)
12. Logo of the Family Health Bureau/Logo of Government of Sri Lanka
13. Wordings "Family Health Bureau, Ministry of Health, Sri Lanka."
14. Quantity (in each box)/Batch/Lot No.
15. Date of manufacture/Date of expiry
16. Storage condition, Name of manufacturer, Country of origin

Packaging:

- 2 rods per set of implants, 10 sets per inner box, 200 inner boxes per carton. The trocar should be separately blister packed. 10 trocars per inner box, 200 inner boxes per carton.
- The cartons should be made of corrugated cardboard with double wall, strength 1400g/ sqm. The corrugated box should be strong and should not lose its shape when stacked during storage.

Delivery/ Shipment:

- Director MCH, Family Health Bureau should be informed 10 days prior to the arrival of shipment.
5. MSD Order List No. **MSD/P/FHB/122/12/S**, SR No. of Item and SPC Indent No. should be indicated in all supply Invoices and packing Lists.
 6. All packages to be stenciled with the relevant MSD Order List Number.
 7. If the items not supplies to schedule we have the right to accept or reject the consignment delivered thereafter.
 8. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement

9.To be delivered in on lot as early as possible.

Sufficient quantity of Samples should be forwarded for evaluation.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of item on instances where the total Tendered Price of item exceeds LKR 5 million. Bid Bond should be submitted together with the tender

Order List

No : MSD/P/FHB/122/12/S

Item	SR	Item Specification	Quantity
1 /	075568	<p>Two rod subdermal Implants (1set)</p> <p>Each rod should contain Levonogestrel 75mg BP/USP. The rod should consist of non absorptive, clinically safe material for subdermal implantation. The disposable trocar should be available for each set.</p> <ol style="list-style-type: none">1. The product should be stable under normal room temperature (30° C -35° C) and humidity (75% -100%) prevailing in Sri Lanka2. The expiry date should not be less than 5 years from the date of manufacturer.3. The supply should be from freshly manufactured stocks and should reach Sri Lanka within 3 months of manufacture. <p>Pack size: 01</p>	7,000 Sets

Delivery : 100%- As early as possible

NUK/ns