ANNEX - 1A

TENDER NO. : **DHS/SUS/87/F/2012**
DATE OF ISSUE : **24TH MAY, 2012**
CLOSING DATE & TIME : 10TH JULY, 2012 AT 09.30 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. **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.**
3. **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.**
4. 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.
5. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price.
6. The volume of the total quantity of each item should be given in cubic meters (m^3).
7. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
8. We reserve the right to reject offers which do not comply above.

Additional 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 recommendation of WHO from the country of Manufacture.
   2. Evidence of pre – qualification by International organizations
      A (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 add the Suppliers expense if there is any suspicion of Quality failure or complaint regarding the product.

Labelling :-
Should contain the following information:

Blister Pack:

10. Date of manufacture, date of expiry and batch/lot No.
11. The logo of the Family Health Bureau, logo of Government of Sri Lanka and the Letters **FHB** should be clearly printed in black

- Storage condition, Name of manufacturer, Country of origin

12. 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

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

Packaging :-

- 1 rod and the applicator should be in a blister pack, 10 blister packs per inner box, 200 inner boxes per carton. The carton 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/121/12/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. In the event an item not supplied to schedule, to ensure continuous availability of same if local purchases are made, any excess payment over indent cost to be deducted when setting payments for supplies made by SPC under normal indent.

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

Samples should be forwarded for evaluation.

ORDER LIST NO. : MSD/P/FHB/121/12/S

ITEM/SR NO.	DESCRIPTION OF ITEM WITH SPECIFICATIONS	QUANTITY REQUIRED
075550	**Single rod subdermal implant in a pre loaded, sterile and disposable applicator (blister pack)** Each rod should contain Etonogestrel 68mg BP/USP. The rod should consist of not absorptive, clinically safe material for subdermal implantation. 1. The product should be stable under normal room temperature (30°C – 35°C) and humidity (75% - 100%) prevailing in Sri Lanka. 2. The expiry date should not be less than 5 years from the date of manufacture. 3. The supply should be from freshly manufactured stocks and should reach Sri Lanka within 3 months of manufacture. Pack Size : None	8,000 Sets

DELIVERY : 100% – As early as possible

NUK/ad