Annex. 4
PRODUCT SPECIFICATIONS
AND
TECHNICAL REQUIREMENTS

THIS DOCUMENT ISTO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN THE RFQ: **GHSC-PSM-TO3-2018-IMP-IDIQ**

I. Product Specifications

Items	**Levonorgestrel-releasing Implant:** Two rod (75 mg levonorgestrel each), sterile	**Etonogestrel-releasing Implant:** One rod (68 mg Etonogestrel), Radiopaque, sterile. Preloaded in a sterile, disposable applicator
Release System	Subdermal, progestin only	Subdermal, progestin only
Strength	150 mg Levonorgestrel (2 rods x 75 mg)	68 mg of Etonogestrel
Use Life	3 - 5 years	3 - 5 years
Packaging	Carton box with 10 x 2 rods/pouch Shipping Carton containing 50 to 100 pouches	Carton box with 1 blister pack, Carton box with 5 blister packs Shipping Carton containing 50 to 100 blister packs
Trocar/Applicator per Implant	Required, including a description	Required, including a description

II. General Product Requirements

The following general product requirements apply to this solicitation for contraceptive implants:

- Finished Pharmaceutical Products must have Stringent Regulatory Authority Approval (SRA)* or be listed in the WHO Prequalification of Medicines Program Finished Pharmaceutical Products Database.

- Trocar/Applicator: In instances where the trocar/applicator is not part of the SRA or WHO PQ approval, trocar/applicator must have US FDA Clearance (510k) or CE mark (SRA). Trocar manufacturer shall conform to the quality standards set by the International Organization for Standardization and/or the US FDA Quality System Regulations. Manufacturer must be quality assured with certifications like ISO 9001:2000 (or above) or ISO 13485 or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certifications(s) included. A copy of the manufacturer(s) certifications(s) must be provided

- Products offered must have a minimum of 36 months shelf-life, as supported by adequate stability data, in accordance with ICH guidelines, and support transport and storage in Climatic Zones IVa and/or IVb, with a preference for Zone IVb.

- The product labeling, physician leaflet, and patient information shall be available at minimum in English language. The Offeror will be responsible for the preparation and availability (including regulatory approval) of French, Spanish, and other languages that may be required throughout the life of the contract and as directed by GHSC-PSM.

**USAID recognized stringent regulatory authorities (SRA): U.S. Food and Drug administration (USFDA), Japanese Ministry of Health, Labor, and Welfare (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA); European Medicines Agency (EMA) and member states admitted to the European Union (EU) prior to 1996 Hague Convention (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and United Kingdom); SwissMedic; Health Canada; and Australia Therapeutic Goods Administration (TGA)*

III. Conformity with Quality and Products Standards

Pharmaceuticals and medical devices procured using US Government funds under GHSC-PSM are restricted commodities and must comply with the guidance as indicated under ADS 312 from the United States Agency for International Development (USAID) Global Health Bureau. The vendor guarantees that the offered items are compliant with the USAID guidance for Pharmaceuticals ADS 312. https://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf

IV. Quality Assurance Provision

The Offeror shall coordinate with USAID's quality assurance contractor, the Global Health Supply Chain Program - Quality Assurance (GHSC-QA), who will implement inspection, sampling, quality assurance testing and acceptance.

V. Pre-Acceptance Sampling and Testing Requirements

The Offeror shall provide requested product documentation for review and acceptance prior to shipment. GHSC-QA reserves the right to sample from the Manufacturer's facility and to perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services conform to the prescribed requirements prior to the acceptance of every lot.

- A Manufacturer Certificate of Analysis is required for all lots procured.

VI. Sampling requirements

When requested, samples from each production lot (50 units) must be sent by the manufacturer to GHSC-QA.

VII. Test method

Finished pharmaceutical products (FPPs) must meet USP, BP or Ph. Eur. compendia, when available. If the eligible FPP test method(s) include non-compendial methods and method transfer was not yet performed, the manufacturer may be requested to provide for method transfer and for each routine test the FPP and reference substances required for performing the laboratory tests.

VIII. Post- Acceptance Inspection

Unless otherwise specified in the contract, each product lot delivered to GHSC-PSM shall comply with all product specifications and test procedures in effect at the time of contract award and throughout the specified shelf-life.

GHSC-QA reserves the right to sample from and perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services continue to conform to the prescribed requirements after product acceptance.

In the event that products are determined to not be fully compliant, the Offeror shall be required to remedy any defects or faults.

IX. Product documentation

Offerors are required to complete **Supplement 1 Pharmaceutical Product Questionnaire** for each Finished Pharmaceutical product offered in accordance with the instructions provided; In instances where the trocar/applicator is not part of the SRA or WHO PQ approval, trocar/applicator offerors are required to complete **Supplement 4: Medical Device Product Questionnaire** in accordance with the instructions provided.

[Offerors shall follow the following guidance: Supplement 2 Instructions for Creating a GHSC-QA Technical Questionnaire Submission and Supplement 3 Instructions to Access and Upload Documentation to GHSC-QA SharePoint Site.

X. Shelf life

As stated above, Finished Pharmaceutical Products offered must have a minimum of 36 months shelf-life, with a preference for 60 months. All goods must be freshly manufactured, and thus have maximum possible shelf-life. Goods should have 85% shelf-life remaining when delivered.

For products offered from stock offerors must clearly indicate the manufacturing date and expiry date.

XI. Shipping Specifications

Please provide estimated weight, dimensions and number of pieces. Please provide documentation for the recommended and required storage and transportation conditions where applicable. For products requiring temperature control (cold chain), ensure data loggers are incorporated with shipment of product, or use validated shipment process.

XII. Packaging Specifications

The contraceptive implants to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The carton will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and ensure the safety, efficacy and quality of the product. Once the Offeror selects a shipping carton size, that size will remain constant throughout the life of the contract.

XIII. Packaging and Packing

Packaging, packing and marking shall be in accordance with all applicable FDA/SRA regulations USAID Marking requirements. **Preference for range of 10/20 Sub-dermal Implants per inner carton, and 50/100 Sub-dermal implants per shipping carton.**

Chemonics reserves the right to require USAID marking as below: The Manufacturer (s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID and can be found at: http://www.usaid.gov/branding/

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.

A list of the emblem suppliers can be found at: http://www.usaid.gov/branding/suppliers

a. Bar coding

Chemonics is implementing GS1 labeling requirements on tertiary packaging (pallet/logistics unit and carton/trade item) during the period of performance of resulting subcontracts. The Offeror will be required to comply with GS1 General Specifications for identification and marking details for orders issued under resulting subcontracts. The Subcontractor may refer to the GS1 Technical Implementation Guide, also located in Annex 1: https://www.ghsupplychain.org/media/532 .