Annex. 4
PRODUCT SPECIFICATIONS
AND
TECHNICAL REQUIREMENTS

THIS DOCUMENT IS TO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN THE RFQ GHSC-PSM-TO3-2019-INJ-IDIQ.

I. Product Description

Type	Presentation	Components
Injectable hormonal contraceptives: Medroxyprogesterone Acetate, Depot 150 mg/mL, in 1mL vial (DMPA IM) & 104 mg/0.65 mL Depot Medroxyprogesterone Acetate (DMPA-SC), Prefilled Uniject device	150 mg/mL progestin contraceptive injectable as a white, aqueous suspension containing medroxyprogesterone acetate in glass vial (1 mL).	• Progestin- The progestin will be medroxyprogesterone acetate, depot injection 150 mg/mL. • Packaging- Product shall be packaged in single dose glass vials. • Intramuscular injection administration. • Minimum shelf-life: 24 months
	104 mg/0.65 mL Depot Medroxyprogesterone Acetate (DMPA-SC), Prefilled Uniject device	• Depot medroxyprogesterone acetate (DMPA-SC) for subcutaneous injection. • Pre-Filled Uniject Device • Single/non re-useable injection system • Minimum Shelf-life: 36 months
Auto-Disable (AD) / Single use Syringe	Sterile, auto-disable syringe with needle.	• Syringes components: Two pieces - barrel and plunger rod. • Syringe material: polypropylene • Needle fixation: Fixed • Needle tube: Stainless Steel • Needle size: 21- 23G • Use: Single-use, disposable • Volume: 1 mL • Quality standards: US FDA 510k or CE mark. • Re-use prevention: Re-use shall be prevented by a locking clip. Re-use prevention location will be at the start of the injection. Re-use prevention type will be 1A. • Shelf-life: 5 years preferred. • Packaging: Packaged in sterile single-unit blister packs that include lot number and expiration date per unit.

Safety Box	5L safety box	• Size: 5L capacity for disposal of 100 auto-disable (AD) syringes. • Material: Safety box shall be impermeable and puncture proof.

II. General Product Requirements

The following general product requirements apply to this solicitation for injectable contraceptives:

Injectable hormonal contraceptive requirements:

- Finished Pharmaceutical Products must have Stringent Regulatory Authority Approval*or be listed in the WHO Prequalification of Medicines Program Finished Pharmaceutical Products Database. **Offerors whose products have not been approved by Stringent Regulatory Authorities or the WHO Prequalification of Medicines Program may provide documentation for products that are: (1) currently under review by the WHO Prequalification of Medicines Program and expected to receive WHO Prequalification within 12 months, as long as evidence of progress towards achieving WHO Prequalification is provided; and/or (2) currently undergoing review by Stringent Regulatory Authorities and expected to receive marketing approval within 12 months, as long as evidence of progress towards achieving marketing approval is provided; and/or (3) currently under review by 2019 WHO Expert Review Panel (ERP).**
- Products offered must have a minimum of 24 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 a 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.

Syringe requirements:

- Manufacturer(s) 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 such as ISO 9001:2012~~1~~5 or ISO 13485:2016 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.
- Product shall have evidence of US FDA Clearance (PMA/510K) or CE Mark (SRA)* Certificate. Medical supplies shall be labeled with manufacturer/distributor information, lot number, manufacturing date and expiration date. A certificate of analysis/conformance shall be provided for each lot procured. For sterile products, a certificate of sterility shall be provided for each lot.
- Preference for products offered to have 60 months shelf-life.

Safety Box requirements:

- Products offered must support the safe handling and disposal of auto-disable (AD) syringes and be impermeable and puncture proof.

*<u>*USAID recognized stringent regulatory authorities (SRA):*</u> *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); Swiss Medic; 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/ADS_312_Help_Document_February_2018_508.pdf

IV. Quality Assurance Provision

According to GHSC-PSM Standard General Contract Terms and Conditions. The Offeror shall coordinate with GHSC'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 inspection

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.

GHSC–QA may increase or decrease the frequency of monitoring and level of testing when warranted by either a significant change in quality or at the sole discretion of GHSC–QA. The purpose is to maintain an acceptable level of confidence in compliance with contract requirements. For purposes of monitoring, GHSC–QA will regularly prepare a Supplier Status Report in order to track the performance of the Manufacturer.

VI. 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 will be requested to provide for method transfer and for each routine test the FPP and reference substances required for performing the laboratory tests.

VII. Lot disposition

The recommendation to GHSC-PSM concerning the disposition of tested lots shall be determined by the results of tests performed by the designated testing laboratory. The testing

provisions of the contract shall be applicable. GHSC–QA will inform the Manufacturer and GHSC-PSM of any tested and quarantined lots that are unacceptable for delivery; conduct failure investigations, and coordinate any re-tests (if appropriate).

VIII. Manufacturer Furnished inspection data

A certificate of analysis/conformance for each lot shall be on record for each lot shipped to GHSC. Individual test reports shall be maintained by the Manufacturers for a length of time equal to five (5) years from the time of acceptance and shall be made available for inspection by GHSC-QA.

IX. 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.

X. Product documentation

Finished Pharmaceutical Product Documentation:

- Manufacturers of Finished Pharmaceutical Products (FPP**) that are currently eligible for procurement through GHSC,** including FPPs that are under final approval, are required to complete **Supplement 1 Pharmaceutical Product Questionnaire: Abbreviated** for each product/presentation offered.
- **New offerors,** for eligibility consideration, are required to complete a technical questionnaire as follow:
    - For offers of FPPs with Stringent Regulatory Authority Approval or listed in the WHO Prequalification of Medicines Program FPP Database offerors shall complete **Supplement 1 Pharmaceutical Product Questionnaire: Abbreviated**
    - All other offerors shall complete **Supplement 2 Pharmaceutical Product Questionnaire**

  The completed questionnaires shall be assembled and submitted to GHSC-QA following instructions provided in Supplement 3: Instructions for Creating and Submitting GHSC-QA Technical Questionnaire]

Auto-Disable (AD) Syringe Documentation:

- Manufacturers of DMPA FPP with currently approved auto-disable (AD) syringes are not required to provide technical documentation of the syringe.
- Current manufacturers of DMPA FPP with proposed new syringes, modifications to the existing syringes and/or new offerors of DMPA are required to complete **Supplement 4 Medical Device Product Questionnaire** for each syringe type offered**.**

The completed questionnaires shall be assembled and submitted to GHSC-QA following instructions provided in Supplement 3 Instructions for Creating and Submitting GHSC-QA Technical Questionnaire]

The following product documentation will be requested as part of any purchase order procurement process that may result from this RFQ:

- A certificate of analysis/conformance for each lot shall be provided to GHSC-QA.
- Additional product documentation may be requested.

XI. Shelf life

All goods must be freshly manufactured, and thus have maximum possible shelf-life. Unless otherwise required in the purchase order, Goods with a maximum possible shelf life of less than 24 months shall have at least 85% of shelf life remaining when delivered. Goods with a maximum possible shelf life of more than 24 months shall have at least 24 months, or 85%, of shelf life remaining whichever is longer, when delivered.

No Goods will be accepted which do not comply with these requirements unless Chemonics has agreed in writing to different requirements, in which case the Goods must strictly comply with those modified requirements.

XII. Packaging and Packing

Products to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The box 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 products.

The following three packaging options may be provided by Offeror for DMPA-IMs:

- **Option 1- Bundled packaging of injectable hormonal contraceptives (DMPA-IM), syringes, AND safety boxes that includes a 1:1 vial to syringe ratio and 100:1 vial to safety box ratio.**
- **Option 2- Bundled packaging of injectable hormonal contraceptives (DMPA-IM) AND syringes that includes a 1:1 vial to syringe ratio.**
- **Option 3- Individual offer for units of injectable hormonal contraceptives (DMPA-IM), syringes, OR safety boxes.**

Note: When bundled packaging, the shelf-life of each of the components in the bundle must be affixed to the carton.

XIII. Global Standards

GHSC-PSM is implementing a requirement for trade item and location, data capture (e.g. barcode labeling) and master data exchange via the GS1 Global Data Synchronization Network (GDSN) during the period of performance of this subcontract. The subcontractor is required to comply with this requirement in full, referenced in "ARTICLE 3. Packing, Export Marking, Preparation for Shipment and Packaging" (Sections D and E) of Annex 1 – General Terms and Conditions of this RFQ.

The subcontractor may refer to the Global Standards Technical Implementation Guideline for Global Health Commodities, V 2.1 for more information: https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

XIV. USAID Marking Requirements

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 .