

Request for Information (RFI)

RFI Number: RFI-GHSC-PSM-EC-2023-09

For the procurement: Emergency Contraceptives

Issuance Date: September 12, 2023

Questions Submitted by: September 18, 2023, by 5:00 pm Washington DC time (EST)

Closing date: September 25, 2023, by 5:00pm, Washington DC time (EST)

For: USAID Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) project

Funded By: United States Agency for International Development (USAID), Contract No./Task Order No. AID- OAA-I-15-00004/AID-OAA-TO-15-00010

Implemented By: Chemonics International Inc.

Attachments:

RFI Annex 1 – Instructions for completing QA documentation: Finished

Pharmaceutical Product Questionnaire: Abbreviated

RFI Annex 2 - ALL.APP.FPP-107.01 Finished Pharmaceutical Product

Questionnaire:Abbreviated

RFI Annex 3 – ALL.WI.GEN-101.00 Instructions for creating and submitting technical documentation to FHI 360

RFI Annex 4 – Additional Procurement Information

RFI Annex 5 – Product Registration

I. Introduction to Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project

The Global Health Supply Chain Program – Procurement and Supply Management (GHSC- PSM) project (alternately referred to herein as “Chemonics” or “GHSC-PSM” or “Buyer”) is an official project of the United States Agency for International Development (USAID) implemented by Chemonics International and its consortium members. The purpose of GHSC- PSM is to ensure uninterrupted supplies of health commodities in support of USG-funded public health initiatives around the world. The project provides direct procurement and supply chain management support to the President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI), and Population and Reproductive Health (PRH). GHSC- PSM supports health programs through the supply of a wide range of health commodities, including contraceptives and condoms, essential drugs; and select commodities for HIV/AIDS, malaria, maternal and child health, and infectious diseases.

II. Objectives and Scope of the RFI

The purpose of this RFI is to create a fair and open process to gather market intelligence regarding the Emergency Contraceptive (EC) market from manufacturers. This will enable the project to meet its objectives under the PRH Task Order. GHSC-PSM is specifically interested in responses to the request for information (RFI) that provide information on **Levonorgestrel 0.75 mg Tablet, 2 Tablets** and **Levonorgestrel 1.5 mg Tablet, 1 Tablet** presentations with a 36-month shelf-life for future procurement eligibility. The analysis of the RFI results will inform preparation for a 2023 request for quotations (RFQ). The documentation provided by manufacturers in response to this RFI will be binding and will provide GHSC-PSM with an indication of parties interested in participating in a future RFQ and of products that meet GHSC-QA eligibility, which will be open to all manufacturers when published.

III. Questions

Questions or requests regarding the technical or administrative requirements of the RFI shall be submitted in writing to the following email addresses: PSMBidTenders@ghsc-psm.org and msimon@ghsc-psm.com.

All correspondence and documents relating to the offer shall be in English. Responses must be submitted no later than the closing date listed in this solicitation.

The deadline for submission of questions is September 18th by 5:00pm Washington DC time (EST). Phone calls will not be accepted. Only the written answers issued by GHSC-PSM will be considered official. Any verbal information received from employees of the project, Chemonics International, Inc. or any other entity will not be considered as an official response to any questions regarding this RFI.

1. Content of requested information.

This RFI invites responses from manufacturers of **Levonorgestrel 0.75 mg Tablet, 2 Tablets** and **Levonorgestrel 1.5 mg Tablet, 1 Tablet** presentations with a 36-month

shelf-life only that are WHO prequalified or approved by USAID recognized stringent regulatory authorities.

All information should be submitted via email to addresses listed above and be as complete as possible.

- **Meeting Product Eligibility QA Requirements:**

Only product/presentations that are outlined above and approved by a Stringent Regulatory Authority as defined by USAID in ADS312sae_060822 (USAID SRA) approved, WHO Prequalified or have a valid ERP approval (Category 1 or 2) shall be considered eligible for procurement.

Suppliers are requested to follow the “**RFI-GHSC-PSM-EC-2023-09 Instructions for completing QA documentation: Finished Pharmaceutical Product Questionnaire: Abbreviated**” attached to this notification to help ensure a successful QA submission for consideration.

- **Alternative FCA pick up location QA Requirements:**

Pharmaceutical suppliers/manufacturers are responsible for ensuring that the integrity of pharmaceutical products are maintained during the shipping and storage processes. GHSC-QA requires that suppliers/manufacturers provide adequate documentation of Good Distribution Storage Practice (or GSP) prior to storing product intended for GHSC procurement at an internal warehouse different from the manufacturing site, in an external pharmaceutical warehouse or a service provider warehouse along the shipping lanes. Such pharmaceutical warehouses shall meet Good Storage and Good Distribution Practices.

Suppliers are requested to disclose alternative pick-up locations (Name, address, provide a description of services) and attach a current valid copy of a GDSP certificate. GDSP certificates can be issued by recognized certification bodies or other accredited bodies or national regulatory authorities following the assessment of a specific warehouse, storage location, wholesaler distributor, etc., certifying the location has been assessed and certified as meeting the requirements of WHO Good Storage and Distribution Practices (or other GDSP applicable regulation in place if applicable). The certificate shall typically include: certificate number, certification body, name and full address of each location certified, scope of certification, certifying authority signature, validity of certificate, and a link or QR code for the user to be able to verify the authenticity of the certificate.

2. [Instructions for submission](#)

The Offerors (alternatively referred to herein as “Subcontractors” or “Suppliers” or “Vendors”) are responsible for ensuring the information is received by GHSC-QA and GHSC-PSM in accordance with the instructions, terms, and conditions described in this RFI.

Submission to GHSC-PSM

Suppliers are requested to complete Annex 4 and Annex 5 and submit to the following email addresses: PSMBidTenders@ghsc-psm.org and msimon@ghsc-psm.com.

All correspondence and documents relating to the offer shall be in English. Responses must be submitted no later than the closing date listed in this solicitation.

The deadline for submission of responses is September 25th by 5:00pm Washington DC time (EST). Phone calls will not be accepted. Only the written answers issued by GHSC-PSM will be considered official. Any verbal information received from employees of the project, Chemonics International, Inc. or any other entity will not be considered as an official response to any questions regarding this RFI.

Submissions to GHSC-QA

Suppliers are requested to follow Instructions for Completing QA Documentation provided in Annex 1, Annex 2, and Annex 3 to help ensure a successful QA submission for consideration.

a) Deadline

Information should be submitted based on the guidelines listed in this RFI, along with properly filled out Annex. Information and all correspondence and documents relating to the offer shall be in English. Information must be sent by email no later than September 25th by 5:00pm Washington DC time (EST).

Please include the RFI reference number RFI-GHSC-PSM-EC-2023-09 in the email subject line.

b) Technical specifications

The information must contain information requested in response to this RFI shall be current as of the closing date for the RFI. After the closing date, any updates to regulatory approvals, manufacturing location, API source or other relevant qualifying information should be provided via the GHSC-QA instructions in the eligibility notification in a timely manner.

c) Confidentiality

Information provided through the RFI will be shared with all stakeholders of the USAID GHSC project, including but not limited to USAID and FHI 360.