GHSC-PSM ARV FY2024[1] PRESOLICITATION NOTICE

SECTION 1: INTRODUCTION

The Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project is an official project of USAID implemented by Chemonics International Inc. and its consortium members. The purpose of GHSC-PSM is to ensure uninterrupted supplies of health commodities in support of U.S. government-funded public health initiatives around the world. The project provides 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.

Purpose. The GHSC-PSM team is currently developing our annual strategic sourcing plan to procure Antiretroviral Drugs (ARVs) for fiscal year 2024 (FY24). The period of the strategy is November 2023 to November 2024. This strategy shall emphasize ARV commodity security, market health, long-term sustainability, a continuation of promoting USAID private sector engagement objectives and for the first time, subject to USAID making adjustments to its policies, procurement from eligible African sources. The purpose of this document is to share an overview of the sourcing strategies under consideration. It also serves as an advance notice to ARV suppliers and their partners to enable them to make necessary preparations in anticipation of the forthcoming release of the FY24 Request for Proposals (RFP).

SECTION 2: OBJECTIVES

ARV Sourcing Objectives. In alignment with PEPFAR's programmatic goals of developing a more sustainable ARV supply chain, GHSC-PSM shall build upon the successes of the D-term procurement program and Vendor Managed Services (VMS) program, with an objective of:

1) Enabling the procurement of ARVs positioned closer to the patient and specifically on the African continent.
2) Reducing order cycle times (measured as order placement to delivery of product to country)
3) Creating opportunities for strategic partnerships between ARV suppliers and PEPFAR supported country stakeholders (government, ministries of health, procurement entities)
4) Regional production of HIV commodities in Sub-Saharan Africa

PEPFAR introduced its Private Sector Engagement policy in 2021, recognizing the significance of private

[1] 1st October, 2023 to 30th September, 2024

sector involvement in mobilizing market-based solutions for sustainable and scalable outcomes. As a result of this policy, USAID was interested to diversify its partner base by including more private enterprises alongside traditional development/implementing partners.

Through our FY24 sourcing objectives, GHSC-PSM shall continue to support this policy through the D-Term and VMS programs, while exploring increased opportunities for the downstream delivery of ARVs (delivery beyond central medical stores). A global RFP shall first be released to source all ARVs for procurement from current eligible ARV sources, for D-TERM and VMS programs (as listed on the GHSC-QA ARV eligibility list).

The regional production of HIV commodities in Sub-Saharan Africa is a new sourcing objective for FY24. In 2022, PEPFAR announced ambitious targets to transition at least two million clients on first-line ARV treatments to African-made products by 2030. The regional production of HIV commodities has been identified as a critical priority in PEPFAR's five-year strategy to ensure the sustainability of the HIV/AIDS response. PEPFAR seeks to make necessary adjustments to its procurement policies to provide increased support to emerging African manufacturers as they scale up their operations. GHSC-PSM, in close collaboration with USAID and other program partners, has been working to develop a long-term roadmap to support this priority. As part of our FY24 sourcing strategy, GHSC-PSM seeks to establish a framework to procure a proportion of Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet (TLD) demand from eligible sources on the African continent who offer the product at a fair market rate. In the event of TLD suppliers on the African continent be added to the GHSC-QA ARV eligibility list in FY24, a subsequent regional RFP may be released after the release of the global RFP.

This document provides a detailed overview and timelines of the ARV Global RFP only. However, as the Regional RFP strategy is still in the initial stages of formulation, further details and information may be shared through a separate communication.

SECTION 3: OVERVIEW OF ARV GLOBAL RFP

Sourcing Strategies Under Consideration. The GHSC-PSM ARV Global RFP is considering the following strategic approaches:

- **Annual Allocation of non-TLD ARVs with fixed pricing for FCA and modified DAP/DDP Incoterms**. For products within this category GHSC-PSM shall continue the annual allocation exercise that establishes a primary, secondary, and where applicable tertiary supplier by PEPFAR country serviced. Country specific allocations shall be established for the ten D-term countries detailed in Annex 1 and Rest of the World. Products listed in the updated ARVs list, detailed on Annex 2, are candidates for consideration for procurement within this strategy.

- **ARVs sourced through open competition, with established fixed/ceiling prices for FCA and modified DAP/DDP Incoterms.** ARVs listed on Annex 3 are candidates for consideration for procurement within this strategy. Products under this strategy will be procured through open competition from eligible suppliers with established IDIQ contracts.

- **Sourcing TLD through the VMS program**. GHSC-PSM intends to procure TLD demand materializing from the Southern African region from the established VMS partners (refer Annex 4 for list of countries in the region). Each partner shall be awarded a market share percentage of the estimated demand, based on the evaluation outcome of the Global RFP. VMS suppliers are required to maintain DDP/DAP eligibility and VMS warehouse eligibility as a pre-requisite for award allocations within this category.

- **Sourcing TLD through Global Allocation from Strategic partners.** GHSC-PSM intends to allocate 85% of the estimated global demand (excluding demand from Southern African region reserved for VMS), to a maximum of five (5) strategic TLD partners. The selected suppliers shall be established as TLD global suppliers. Based on the evaluation outcome, successful partners will be awarded a market share percentage of the estimated demand.

Note: Suppliers eligible to deliver ARVs under DAP or DDP incoterms shall receive a competitive advantage to over those who are not. DAP and DDP rates shall be established for a 1 -year period for air (by four weight bands), sea (by fixed container rate) and land (by fixed full truck load rate).

Global RFP Sourcing Timelines. Below are key milestones and tentative dates planned for the Global RFP

Release Pre-solicitation Notification	**6-Jul-23**
Release of GHSC-QA RFP for Product Eligibility and DDP/DAP Eligibility determination	7-Jul-23
Deadline for submission of suppliers' questions on GHSC-QA RFP	13-Jul-23
ARV Supplier Conference (Virtual)	2-Aug-23
Release of GHSC-PSM Global RFP	4-Aug-23
Close of GHSC-QA RFP for Product Eligibility and DDP/DAP Eligibility determination	10-Aug-23
Deadline for submission of suppliers' questions on GHSC-PSM Global RFP	12-Aug-23
Deadline for GHSC-PSM to respond to submitted questions/clarifications from suppliers	22-Aug-23
Close of GHSC-PSM Global RFP	4-Sep-23
Estimated Sub-contract Execution	17-Nov-23

Dates above are tentative and may be modified at the sole discretion of Chemonics. Chemonics shall share updates as dates become finalized.

SECTION 4: QUALITY ASSURANCE (QA) REQUIREMENTS FOR GLOBAL RFP

1. Meeting Product Eligibility QA Requirements:

Only product/presentations that are outlined in Annex 2 and Annex 3 of this document, and are US FDA approved or tentatively approved (NDA/ANDA) shall be considered eligible for procurement.

Suppliers are requested to follow the **Instructions for completing Finished Pharmaceutical Product Questionnaire: Abbreviated** attached to this notification (Annex 5) to help ensure a successful submission for consideration.

2. **DAP/DDP Eligibility QA Requirements:**

Suppliers offering ARVs with DAP/DDP incoterms are required to demonstrate that they, and their partners, have the experience, internal processes, and adequate quality assurance (QA) oversight to maintain product integrity while product is within their chain of custody, and including while the products are in transit between the manufacturer and the recipient. If health commodities are staged at a secondary facility or warehouse closer to a port or between manufacturing sites prior to export, offerors should have internal procedures that extend oversight of product integrity to these locations as well.

Key aspects of the quality management systems (QMSs) of the supplier and the supplier's partners that may determine eligibility and shall be evaluated include:

- Selecting, vetting, and monitoring 3PLs and 4PLs (and staging locations such as secondary facilities or warehouses) to ensure that product integrity is maintained while the product is in their custody.
- Managing and reporting product quality incidents (e.g., temperature excursions) and recalls, including the role of all corresponding 3PLs (and staging locations such as secondary facilities or warehouses) in ensuring product integrity is maintained while the product is in their custody.
- An overview of key performance indicators (KPIs) used by the supplier to monitor and manage performance.

Suppliers are requested to follow the **Instructions for Completing D-Terms Technical Questionnaire** attached to this notification (Annex 6) to help ensure a successful submission for consideration.

GHSC-PSM, on behalf of GHSC-QA, intends to release the GHSC-QA RFP by 7th July, 2023, that shall cover both product eligibility determination and DDP/DAP eligibility determination. Based on the responses to GHSC-QA RFP, GHSC-QA will provide GHSC-PSM with evaluation scoring for eligible suppliers and the scoring shall be included as part of the overall evaluation criteria for the Global ARV RFP.

Annex 1: Target D-Term Countries List

Democratic Republic of the Congo
Eswatini
Haiti
Kenya
Mozambique
Nigeria
Tanzania
Uganda
Zambia
Zimbabwe

Annex 2: Potential ARVs planned to be sourced through annual allocation process.

Abacavir/Lamivudine 120/60 mg Dispersible Tablet, 30 Tablets
Abacavir/Lamivudine 120/60 mg Dispersible Tablet, 60 Tablets
Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets
Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets
Darunavir 150 mg Tablet, 240 Tablets
Darunavir 75 mg Tablet, 480 Tablets
Darunavir 600 mg Tablet, 60 Tablets
Dolutegravir 10 mg Scored Dispersible Tablet, 90 Tablets
Dolutegravir 50 mg Tablet, 30 Tablets
Dolutegravir 50 mg Tablet, 90 Tablets
Dolutegravir/Emtricitabine/Tenofovir AF (TAFED) 50/200/25 mg Tablet, 30 Tablets
Dolutegravir/Emtricitabine/Tenofovir AF (TAFED) 50/200/25 mg Tablet, 90 Tablets
Dolutegravir/Lamivudine/Abacavir (ALD) 50/300/600 mg Tablet, 30 Tablets
Dolutegravir/Lamivudine/Tenofovir DF (TLD) 50/300/300 mg Tablet, 180 Tablets
Dolutegravir/Lamivudine/Tenofovir DF (TLD) 50/300/300 mg Tablet, 90 Tablets
Efavirenz/Lamivudine/Tenofovir DF (TLE400) 400/300/300 mg Tablet, 90 Tablets
Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets
Lamivudine 10 mg/mL Solution w/ Syringe, 240 mL
Lamivudine 150 mg Tablet, 60 Tablets
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets
Lamivudine/Zidovudine 30/60 mg Dispersible Tablet, 60 Tablets
Nevirapine 10 mg/mL Suspension w/ Syringe, 100 mL
Nevirapine 10 mg/mL Suspension, 100 mL
Nevirapine 50 mg Dispersible Tablet, 60 Tablets
Raltegravir 100 mg Granules for Suspension, 60 Sachets
Ritonavir 100 mg Film Coated Tablet, 60 Tablets
Ritonavir 25 mg Tablet, 30 Tablets
Zidovudine 10 mg/mL Solution w/ Syringe, 240 mL
Zidovudine 10 mg/mL Solution, 240 mL

Annex 3: Potential ARVs planned to be sourced through open competition

Tenofovir DF 300 mg Tablet, 30 Tablets
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets
Lopinavir/Ritonavir 40/10 mg Oral Granules for Suspension, 120 Sachets

Annex 4: Southern African Countries

Angola
Botswana
Democratic Republic of the Congo (Lubumbashi, Kolwezi)
Eswatini
Lesotho
Malawi
Mozambique
Namibia
Zambia
Zimbabwe

Annex 5

Instructions for completing Finished Pharmaceutical Product Questionnaire: Abbreviated

Only offers of products outlined in the RFP and meeting eligibility criteria outlined in the RFP will be considered eligible for review. FHI 360 (through the U.S. Agency for International Development [USAID] Global Health Supply Chain-Quality Assurance Program [GHSC-QA] will provide GHSC-PSM with a quality assurance (QA) score that will be included as part of the overall offer evaluation criteria. In Ivalua, offerors are required to confirm that they have read and understood the instructions for creating a GHSC- QA Technical Questionnaire Submission and confirm that they have uploaded the required documentation to the GHSC-QA website in accordance with *ALL.WI.GEN-101.00 Instructions for Creating and Submitting Technical Documentation to FHI 360*.

Carefully read the instructions below to help ensure an accurate completion of *ALL.APP.FPP-107: Finished Pharmaceutical Product Questionnaire: Abbreviated*.
Offerors of products/manufacturing sites/presentations **not evaluated** by GHSC-QA: Complete *ALL.APP.FPP-107.00 Finished Pharmaceutical Product Questionnaire- Abbreviated* and provide the information requested.

Eligible suppliers of products/manufacturing sites/presentations **evaluated** by GHSC-QA **and whose previously submitted technical documentation remains valid** and **that do not have updates to report**, are requested to complete the following sections of *ALL.APP.FPP-107.00M Finished Pharmaceutical Product Questionnaire- Abbreviated* for each offered product/manufacturing site and product presentation:

Section 1.0 Applicant Information
Section 2.0 Product Identification
Section 7.0 Product Quality Review
Section 10 Authorization and Commitment

Eligible suppliers that have **technical updates** to report are requested to complete the relevant sections in *ALL.APP.FPP-107.00 Finished Pharmaceutical Product Questionnaire- Abbreviated* to provide updated information and documentation (e.g., updated FPP Specifications and Analytical Methods, nitrosamine risk assessment; updated FPP packaging, labelling, updated stability data to support FPP Shelf-life or storage conditions, updated API information). The following sections are required to be completed regardless of the technical update incorporated:

Sections 1 Applicant Information,
Section 2 Product Identification, Section
7 Product Quality Review
Section 10: Authorization and Commitment

Offers that do not include the appropriate authorization and commitment signatures may not be considered for review.

Annex 6

Instructions for Completing D-Terms Technical Questionnaire

Only delivery at place (DAP) and delivery duty paid (DDP) offers meeting the criteria outlined in the RFP will be considered eligible for review. FHI 360 (through the U.S. Agency for International Development [USAID] Global Health Supply Chain-Quality Assurance Program [GHSC-QA] will provide GHSC-PSM with a quality assurance (QA) score that will be included as part of the overall offer evaluation criteria. In Ivalua, offerors are required to confirm that they have read and understood the instructions for creating a GHSC-QA Technical Questionnaire Submission and confirm that they have uploaded the required documentation to the GHSC-QA website in accordance with *ALL.WI.GEN-101.00 Instructions for Creating and Submitting Technical Documentation to FHI 360*.

Carefully read the instructions below to help ensure and accurate completion of *ALL.APP.GEN-226 Technical Questionnaire Delivery at Place (DAP) and Delivery Duty Paid (DDP) Incoterms and Vendor Managed Solutions (VMS).*

New offerors of DAP and DDP shipments shall complete Section 2.0 OFFEROR: QUALITY ASSURANCE OVERSIGHT FOR CONTRACTED LOGISTICS PROVIDER (3PL) AND/OR WAREHOUSE PROVIDER (VMS) AND Section 3.0 DAP AND DDP INCOTERM DELIVERY, including all the subsections, and include the appropriate attachments as requested.

Currently eligible offerors of DAP and DDP shipments **that have updated their QA oversight for DDP and DAP services** since becoming eligible shall complete the relevant sections Section 2.0 OFFEROR: QUALITY ASSURANCE OVERSIGHT FOR CONTRACTED LOGISTICS PROVIDER (3PL) AND/OR WAREHOUSE PROVIDER (VMS) including the subsections related to the updates and include the appropriate attachments as requested.

Currently eligible offerors of DAP and DDP shipments that **have updated the currently eligible third-party logistics providers (3PLs)** shall complete the relevant sections in Section 3.0 DAP and DDP INCOTERM DELIVERY, 3.1 Subcontracted Third-Party Logistics Provider (3PL) related to the updates and include the appropriate attachments as requested.

Currently eligible offerors of DAP and DDP shipments that are **interested in adding additional 3PLs** or **re-evaluation of 3PLs previously determined to be ineligible** shall complete Section 3.0 DAP and DDP INCOTERM DELIVERY and 3.1 Subcontracted Third-Party Logistics Provider (3PLs), in its entirety, and include the appropriate attachments as requested.

In addition to the appropriate sections above**, All offerors** shall complete Section 1.0 APPLICANT INFORMATION and Section 5.0 AUTHORIZATION AND COMMITMENT. When no updates are required, the offeror shall add a statement to the authorization and commitment specifying that "no updates are required." **_Offers that do not include the appropriate applicant information and authorization and commitment signatures may not be considered for review**.
This RFQ is specific for DAP and DDP shipments, so **all offerors** are cautioned **not to complete** Section 4.0 Vendor Managed Services (VMS) and its associated subsections as these are not relevant to the current RFP.