

Request for Quotations (RFQ)

RFQ Number: PSM-OPS-2015

Issuance Date: 07/25/2022

Deadline for Offers: 08/08/2022

Description: Incineration of unusable pharmaceutical products (PPI)

For: Global Health Supply Chain Program (GHSC) – Procurement and Supply Management (PSM)

Funded By: United States Agency for International Development (USAID),
Contract No. AID-OAA-I-15-00004; Task Order No. AID-OAA-TO-15-00007.
AID-OAA-TO-15-000010, and AID-OAA-TO-16-00018

Implemented By: Chemonics Foundation Haiti

Point of Contact: PSMHaitiachat@ghsc-psm.org Airport Industrial Parc Fleuriot Warehouse # 119

***** ETHICAL AND BUSINESS CONDUCT REQUIREMENTS *****

Chemonics is committed to integrity in procurement, and only selects suppliers based on objective business criteria such as price and technical merit. Chemonics expects suppliers to comply with our Standards of Business Conduct, available at <https://www.chemonics.com/our-approach/standards-business-conduct/>.

Chemonics does not tolerate fraud, collusion among offerors, falsified proposals/bids, bribery, or kickbacks. Any firm or individual violating these standards will be disqualified from this procurement, barred from future procurement opportunities, and may be reported to both USAID and the Office of the Inspector General.

Employees and agents of Chemonics are strictly prohibited from asking for or accepting any money, fee, commission, credit, gift, gratuity, object of value or compensation from current or potential vendors or suppliers in exchange for or as a reward for business. Employees and agents engaging in this conduct are subject to termination and will be reported to USAID and the Office of the Inspector General. In addition, Chemonics will inform USAID and the Office of the Inspector General of any supplier offers of money, fee, commission, credit, gift, gratuity, object of value, or compensation to obtain business.

Offerors responding to this RFQ must include the following as part of the proposal submission:

- Disclose any close, familial, or financial relationships with Chemonics or project staff. For example, if an offeror's cousin is employed by the project, the offeror must state this.
- Disclose any family or financial relationship with other offerors submitting proposals. For example, if the offeror's father owns a company that is submitting another proposal, the offeror must state this.
- Certify that the prices in the offer have been arrived at independently, without any consultation, communication, or agreement with any other offeror or competitor for the purpose of restricting competition.
- Certify that all information in the proposal and all supporting documentation are authentic and accurate.
- Certify understanding and agreement to Chemonics' prohibitions against fraud, bribery and kickbacks.

Please contact **Florence Duperval Guillaume** with any questions or concerns regarding the above information or to report any potential violations. Potential violations may also be reported directly to Chemonics' Washington office through the contact information listed on the website found at the hyperlink above.

Section 1: Instructions to Offerors

Introduction: The purpose of the Global Health Supply Chain - Procurement and Supply Management (GHSC-PSM) single award IDIQ contract is to ensure uninterrupted supplies of health commodities to prevent suffering, save lives, and create a brighter future for families around the world. The IDIQ has three task orders that directly support the President's Emergency Plan for AIDS Relief (PEPFAR) and USAID's population and reproductive health program. We are providing health commodity procurement services and systems strengthening technical assistance that encompass all elements of a comprehensive supply chain. As part of project activities, the GHSC-PSM requires the service of Incineration of unusable pharmaceutical products (PPI or UPP). The purpose of this RFQ is to solicit quotations for this service.

Offerors are responsible for ensuring that their offers are received by Chemonics in accordance with the instructions, terms, and conditions described in this RFQ. Failure to adhere with instructions described in this RFQ may lead to disqualification of an offer from consideration.

1. **Offer Deadline and Protocol:** Offers must be received no later than **4:00 PM** local Eastern time on **August 8, 2022**, by email or by hard copy delivery to the GHSC-PSM office. Any emailed offers must be emailed to **PSMHaitiAchat@ghsc-psm.org**. Any hard copy deliveries must be stamped and signed by the offeror's authorized representative and delivered to the GHSC-PSM Office located at **Airport Industrial Parc Fleuriot Warehouse # 118**.

Please reference the RFQ number in any response to this RFQ. Offers received after the specified time and date will be considered late and will be considered only at the discretion of Chemonics.

2. **Questions:** Questions regarding the technical or administrative requirements of this RFQ may be submitted no later than 4:00 pm local Eastern time on **August 2, 2022**, by email to **PSMHaitiAchat@ghsc-psm.org**. Questions must be submitted in writing; phone calls will not be accepted. Questions and requests for clarification—and the responses thereto—that Chemonics believes may be of interest to other offerors will be circulated to all RFQ recipients who have indicated an interest in bidding.

Only the written answers issued by Chemonics will be considered official and carry weight in the RFQ process and subsequent evaluation. Any verbal information received from employees of Chemonics, or any other entity should not be considered as an official response to any questions regarding this RFQ.

Specifications: Section 3 contains the technical specifications of the required service.

Please note that, unless otherwise indicated, stated brand names or models are for illustrative description only. An equivalent substitute, as determined by the specifications, is acceptable.

Quotations: Quotations in response to this RFQ must be priced on a fixed-price, all-inclusive basis, including delivery and all other costs. Pricing must be presented in **Gourdes or US Dollars**. Offers must remain valid for **not less than thirty (30) calendar days** after the offer deadline. Offerors are requested to provide quotations on their official quotation format or letterhead.

In addition, offerors responding to this RFQ are requested to submit the following:

- Organizations responding to this RFQ are requested to submit a copy of their official registration or business license or their “Patente”.
 - Technical offer must include:
 - A brief presentation of the company/institution
 - Experience with destruction of UPPs
 - Description and technical specifications of their equipment indicating the range of temperatures for its operation
 - The procedure the institution follows for incineration of pharmaceuticals
 - Incinerator capacity in Tons per batch
 - Frequency in which the incinerator could be used
 - Description of how they will proceed to destroy the UPPs per the requirement of the scope of work (see Section 3) – any requirements your organization has for the destruction of UPPs. The technical offer should not be longer than 3 pages.
 - Storage capacity to take UPPs for processing.
 - Financial offer must be provided separately from the technical offer.
4. **Delivery:** As part of its response to this RFQ, each offeror is expected to provide an estimate (in calendar days) on how long it will take to destroy 1200 Kg every time we deliver UPPs to them - The destruction timeframe (after receipt of UPPs). The estimate presented in an offer in response to this RFQ must be upheld in the performance of any resulting contract.
5. **Source/Nationality/Manufacture:** All goods and services offered in response to this RFQ or supplied under any resulting award must meet **USAID Geographic Code 935** in accordance with the United States Code of Federal Regulations (CFR), [22 CFR §228](#). The cooperating country for this RFQ is Haiti.

Offerors may not offer or supply any commodities or services that are manufactured or assembled in, shipped from, transported through, or otherwise involving any of the following countries: Cuba, Iran, North Korea, Syria.

Any and all items that are made by Huawei Technology Company, ZTE Corporation, Hytera Communications Corporation, Hangzhou Hikivision Digital Technology Company, Dahua Technology Company will not be accepted. If quotes include items from these entities, please note that they will be deemed not technically responsive and excluded from competition.”

6. **Environmental Compliance:** The Subcontractor shall follow the established Environmental Risk and Occupational Health and Safety Compliance Plan (EHSCP) in order to comply with USAID requirements for the GHSC-PSM project. The purpose of the EHSCP is to monitor environmental impact of the potential activities and define mitigation actions to be implemented. Using the prescriptions of the EHSCP the Subcontractor shall dutifully follow and implement all preventive and mitigation measures during all phases of the project. The Subcontractor shall also maintain on file and provide to Chemonics at the end of the subcontract, the monitoring and evaluation logs associated with the various activities of the project. The Environmental Risk and Occupational Health and Safety Compliance Plan Tracking Tables for this project are provided under Section 3.
7. **Warranty:** N/A.
8. **Taxes and VAT:** The USAID funded project under which this procurement is financed does not permit the financing of any taxes, TCA, tariffs, duties, or other levies imposed by any laws in effect

in the Cooperating Country, and in accordance with the bilateral agreement between the Government of the United States and the Government of Haiti, Chemonics will submit the subsequent subcontract for exemption by the Cooperating Country government.

Therefore, Offerors are requested to submit quotations with any taxes, TCA, tariffs, duties, or other levies imposed by the laws in effect in the Cooperating Country(ies) clearly identified separately from the offered price.

Any resultant subcontract shall be priced as free and exempt from any taxes, TCA, tariffs, duties, or other levies imposed by the laws in effect in the Cooperating Country(ies). The Offeror shall not charge any host country taxes, TCA, tariffs, duties, levies, etc. from which this USAID program is exempt. In the event that any exempt charges are paid by the Subcontractor, they will not be reimbursed to the Subcontractor by Chemonics unless approved in advance in writing by Chemonics. The Subcontractor shall immediately notify Chemonics if any such exempt taxes are assessed against the Subcontractor or its subcontractors/Subcontractors at any tier.

Under any resultant subcontract, the Subcontractor shall be responsible for payment of all applicable taxes, as prescribed under the applicable laws, associated with wages/salaries/compensation for services rendered by individuals employed by the Subcontractor and who are directed to work as required under this Subcontract. The Subcontractor is liable for payment of all applicable taxes associated with revenues (profit), and other such taxes, fees, or dues for which the Subcontractor is normally responsible as a result of operating its business.

9. **DUNS Number:** Companies or organizations, whether for-profit or non-profit, shall be requested to provide a Data Universal Numbering System (DUNS) number if selected to receive an award in response to this RFQ valued greater than or equal to USD\$30,000 (or equivalent in other currency). If the Offeror does not have a DUNS number and is unable to obtain one before proposal submission deadline, Offeror shall include a statement noting their intention to register for a DUNS number should it be selected as the successful offeror or explaining why registration for a DUNS number is not possible. Contact Dun & Bradstreet through this webform to obtain a number: <https://fedgov.dnb.com/webform>. Further guidance on obtaining a DUNS number is available from Chemonics upon request.
10. **Eligibility:** By submitting an offer in response to this RFQ, the offeror certifies that it and its principal officers are not debarred, suspended, or otherwise considered ineligible for an award by the U.S. Government. Chemonics will not award a contract to any firm that is debarred, suspended, or considered to be ineligible by the U.S. Government.
11. **Evaluation and Award:** The award will be made to one or two responsible offerors whose offer follows the RFQ instructions, meets or exceeds the minimum required technical specifications, and are judged to be the best values based on a lowest-price, technically acceptable basis.

Please note that if there are significant deficiencies regarding responsiveness to the requirements of this RFQ, an offer may be deemed “non-responsive” and thereby disqualified from consideration. Chemonics reserves the right to waive immaterial deficiencies at its discretion.

Best and final offer quotations are requested. It is anticipated that awards will be made solely on the basis of these original quotations. A contract may be awarded to more than one offeror if several offerors are found to meet the minimum required technical specifications. However, Chemonics reserves the right to conduct any of the following:

- Chemonics may conduct negotiations with and/or request clarifications from any offeror prior to award.

- While preference will be given to offerors who can address the full technical requirements of this RFQ, Chemonics may issue a partial award or split the award among various suppliers, if in the best interest of the GHSC-PSM Project.
- Chemonics may cancel this RFQ at any time.

Please note that in submitting a response to this RFQ, the offeror understands that USAID is not a party to this solicitation and the offeror agrees that any protest hereunder must be presented—in writing with full explanations—to the GHSC-PSM Project for consideration, as USAID will not consider protests regarding procurements carried out by implementing partners. Chemonics, at its sole discretion, will make a final decision on the protest for this procurement.

12. Terms and Conditions: This is a Request for Quotations only. Issuance of this RFQ does not in any way obligate Chemonics, the GHSC-PSM Project, or USAID to make an award or pay for costs incurred by potential offerors in the preparation and submission of an offer.

This solicitation is subject to Chemonics' standard terms and conditions. Any resultant award will be governed by these terms and conditions; a copy of the full terms and conditions is available upon request. Please note the following terms and conditions will apply:

- Chemonics' standard payment terms are net 30 days after receipt and acceptance of any commodities or deliverables. Payment will only be issued to the entity submitting the offer in response to this RFQ and identified in the resulting award; payment will not be issued to a third party.
- Any award resulting from this RFQ will be firm fixed price, in the form of a **purchase order**.
- No commodities or services may be supplied that are manufactured or assembled in, shipped from, transported through, or otherwise involving any of the following countries: Cuba, Iran, North Korea, Syria.
- Any international air or ocean transportation or shipping carried out under any award resulting from this RFQ must take place on U.S.-flag carriers/vessels.
- United States law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. The supplier under any award resulting from this RFQ must ensure compliance with these laws.
- The title to any goods supplied under any award resulting from this RFQ shall pass to Chemonics following delivery and acceptance of the goods by Chemonics. Risk of loss, injury, or destruction of the goods shall be borne by the offeror until title passes to Chemonics.

Section 2: Offer Checklist

To assist offerors in preparation of proposals, the following checklist summarizes the documentation to include an offer in response to this RFQ:

- Cover letter, signed by an authorized representative of the offeror (see Section 4 for template)
- Technical Offer (see section 3)
- Financial Offer Financial offer must be provided separately from the technical offer.
- Copy of offeror's registration or business license (see Section 1.3 for more details)

Section 3: Specifications and Technical Requirements

The table below contains the technical requirements of the commodities/services. Offerors are requested to provide quotations containing the information below on official letterhead or official quotation format. In the event this is not possible, offerors may complete this Section 3 and submit a signed/stamped version to Chemonics.

| Line Item | Description and Specifications | Qty | Unit | Unit Price | Total Price |
|-----------|---|------|------|------------|-------------|
| 1 | Incinération de PPIs dans un incinérateur à température de fonctionnement de 880 degrés Celsius à 1200 degrés Celsius, avec chambre de combustion rotative et capacité de destruction entre 150 Kg/heure à 500 Kg/heure avec une capacité de charge supérieure ou égale à 150 kg. | 1200 | kg | | |
| | | | | | |
| | Subtotal: | | | | |
| | Other Costs (Describe: _____): | | | | |
| | GRAND TOTAL : | | | | |

DESCRIPTIF DU SERVICE

Chemonics International Inc.

Descriptif du Service

TITRE : *Incinération des Produits pharmaceutiques inutilisables (PPI).*

PROJET : *GHSC-PSM / Chemonics Foundation Haiti*

CONTEXTE :

Une gestion inadéquate et surtout une destruction inappropriée des produits pharmaceutiques périmés et/ou inutilisables représentent une menace considérable pour l'environnement et le maintien de l'état de santé de la population. Pour mitiger ces risques, le ministère de la Santé Publique et de la Population (MSPP) supporté par le Projet Global Health Supply Chain Program and Procurement Supply Management (GHSC-PSM) de l'USAID s'est engagé à travers le Plan opérationnel national de gestion des PPI 2021-2025,

à normaliser le processus de gestion de ces produits en Haïti. Selon les recommandations de l'OMS adoptées par le MSPP, la plupart des PPI peuvent être incinérés à 850°C.

Dans le cadre de son appui à la mise en œuvre effective des activités du plan opérationnel national pour la gestion des PPIs et du SNADI (système national d'approvisionnement et de distribution des intrants), un support est offert par le Projet GHSC-PSM pour la collecte, le stockage et l'élimination finale des PPI (spécifiquement ceux générés par les sites soutenus par le Gouvernement américain) au niveau local sous le leadership de la DPMMT.

Dans ce contexte, le Projet souhaite pour l'année fiscale 2022, supporter l'élimination des PPI collectés au niveau des institutions sanitaires et de l'entrepôt central du Projet, dans le respect des normes de destruction nationales et internationales en vigueur.

Ainsi, conformément au plan opérationnel national de gestion des PPI 2021-2025, le projet requiert les services d'une institution possédant un espace de stockage, du personnel adéquat et un incinérateur répondant aux attentes suivantes :

Caractéristique incinérateur :

- Incinérateur à une température de fonctionnement comprise entre 800 degrés à 1200 degrés Celsius.
- Incinérateur à chambre de combustion rotative.
- Capacité de destruction varie entre 150 kg / h à 500 kg / h.
- Capacité de charge supérieur ou égale 150 kg.
- Possédant la main d'œuvre pour assurer le brûlage des produits.
- Espace de stockage varie entre 600 à 1000 m²
- Possédant un espace facilitant l'emplacement de deux conteneurs de 40 pieds ou 20 pieds.

L'institution devra de concert avec la DPMMT et GHSC-PSM dresser et signer des procès-verbaux après chaque opération de traitement et d'élimination des PPI livrés par le Projet, dans le respect des normes en vigueur. Les copies de ces procès-verbaux seront partagées pour archivage avec les acteurs concernés et seront servis pour effectuer les paiements.

DURÉE DU CONTRAT

Un mois renouvelable.

Annexe 1:

Modèle de bordereau de destruction des PPIs

Annexe 2:

Draft Environmental Risk and Occupational Health and Safety Compliance Plan

Section 4: Offer Cover Letter

The following cover letter must be placed on letterhead and completed/signed/stamped by a representative authorized to sign on behalf of the offeror:

To: Chemonics/GHSC-PSM, Airport Industrial Park Fleuriot Warehouse # 118

Reference: RFQ No. **PSM-OPS-2015**

To Whom It May Concern:

We, the undersigned, hereby provide the attached offer to perform all work required to complete the activities and requirements as described in the above-referenced RFQ. Please find our offer attached.

We hereby acknowledge and agree to all terms, conditions, special provisions, and instructions included in the above-referenced RFQ. We further certify that the below-named firm—as well as the firm’s principal officers and all commodities and services offered in response to this RFQ—are eligible to participate in this procurement under the terms of this solicitation and under USAID regulations.

Furthermore, we hereby certify that, to the best of our knowledge and belief:

- We have no close, familial, or financial relationships with any Chemonics or GHSC-PSM project staff members;
- We have no close, familial, or financial relationships with any other offerors submitting proposals in response to the above-referenced RFQ; and
- The prices in our offer have been arrived at independently, without any consultation, communication, or agreement with any other offeror or competitor for the purpose of restricting competition.
- All information in our proposal and all supporting documentation is authentic and accurate.
- We understand and agree to Chemonics’ prohibitions against fraud, bribery, and kickbacks.

We hereby certify that the enclosed representations, certifications, and other statements are accurate, current, and complete.

Authorized Signature: _____

Name and Title of Signatory: _____

Date: _____

Company Name: _____

Company Address: _____

Company Telephone and Website: _____

Company Registration or Taxpayer ID Number: _____

Company DUNS Number: _____

Does the company have an active bank account (Yes/No)? _____

Official name associated with bank account (for payment): _____

Section 5 – EHSCP

ACTIVITY DATA

Project/activity data

| | |
|---|--|
| Project/ Activity Name: | Haiti Disposal of Unusable Pharmaceutical products in country |
| Implementation Start/End: | March 2022 – December 2022 |
| Contract/Award Number: | GHSC-PSM in Haiti/ AID-OAA-I-15-00004, AID-OAA-TO-15-00007, AID-OAA-TO-15-00010, AID-OAA-TO-16-00018 |
| Implementing Partner(s): | Chemonics |
| Geographic Location(s): | Haiti |
| GHSC Tracking ID/link of Other, Related Analyses: | Amendment 2: GHSC-PSM S-IEE GH-20-10467 Amendment 1: GHSC-PSM IEE GH-17-010 Parent IEE: GHSC Programmatic IEE GH-13-15 |
| GHSC-PSM EMMP ID code | Link to GHSC-PSM EMMP on USAID ECD |

Organizational/administrative data

| | |
|--|---|
| Implementing Operating Unit(s): | GHSC-SM in Haiti Field Office |
| Approving Environmental Compliance Specialist: | Janine Berger |
| Prepared by: | Michel Odera Junior, Waste Management Officer |
| Date Prepared: | |
| Submitted by: | |
| Date Submitted: | |

DEFINITIONS

| Term | Definition |
|--|---|
| Incineration | A method of heat treatment of waste consisting of combustion (technology and temperature varying according to the nature of the waste) and treatment of fumes. |
| Personal Protective Equipment (PPE): | Clothing or accessories used to protect the body or part of the body from a specific hazard. |
| Pharmaceutical Waste or Unusable Pharmaceutical Products (UPP) | Pharmaceutical drugs or medicines that can no longer be used because of being expired, withdrawn, recalled, damaged, or contaminated, or for any other reason. |
| Waste | Any unwanted or unusable materials that are discarded after primary use because of being considered worthless, defective, and/or of no other use or value. |
| Waste Collection | The collection of waste commodities from points of generation and their transport to an interim on-site storage location, an on-site treatment and disposal system, or a vehicle for offsite transport and disposal. |
| Waste Treatment | The use of processes to convert wastes that are considered or regulated as being hazardous, toxic, infectious waste, radiological, pathological, physically dangerous, and the like to a residue that is considered safe and suitable for general landfill disposal. |
| Hazardous Waste | Disposed chemicals, products, and materials that are defined as being hazardous under regulations and/or that exhibit hazardous characteristics of flammability or ignitability, corrosively, reactivity, and toxicity. |
| Unusable Medical Product | Disposed, noninfectious, non-contaminated, and nonhazardous products or items used in patient care or medical research activities, such as disposed glass and plastic laboratory ware, empty tubes and vials, syringes, packaging materials, and PPE, such as gloves, masks, and gowns. |

I. INTRODUCTION

The Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) is an official project of the United States Agency for International Development (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 USG-funded public health programs, including but not limited to, HIV/AIDS, Malaria, Family Planning, and Maternal & Child Health initiatives around the world, including Haiti. 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), Population and Reproductive Health (PRH), and Maternal and Child Health (MCH).

Specifically in Haiti, the United States Government, through GHSC-PSM, funds procurement, supply, management, and technical assistance under a range of public health initiatives, including HIV/AIDS, Family Planning, and Maternal & Child Health commodities.

The Ministry of Public Health and Population (MSPP) has placed the strengthening of the national supply and distribution system among its priorities for several years. Within the specific framework of the management of Unusable Pharmaceutical Products (UPP), a National Operational Plan for the Management of Unusable Pharmaceutical Products has been adopted by the MSPP with a view to guaranteeing the implementation of operations in accordance with national and international standards in force. This Plan brings together a set of interventions aimed at facilitating the safe treatment of UPPs in Haiti.

The UPP are expired or tampered products that the project collects from U.S. government-supported health institutions or products that have ended up in the central warehouse before being distributed to the health institutional level. The expired products resulted from lower local consumption of commodities compared to when the forecasting exercises were completed. Prior to each distribution cycle the Supply Chain Monitors collect the 3-month commodities needs from health facilities that may request lower quantities than the projected amounts in the annual forecasting exercise. The tampered and damaged products result from changes in therapeutic protocols for certain products, overestimated amounts during forecasting or at the facilities level, including temperature excursions.

2. SCOPE OF WORK

In support of the Ministry of Public Health and Population (MSPP) in Haiti and to strengthen national capacities for treatment and disposal of unusable pharmaceuticals, the Global Health Supply Chain Program-USAID-funded Procurement and Supply Management (GHSC-PSM), through its Waste Pharmaceuticals Management Unit, will be processing the destruction of waste products in coordination with the Directorate of Pharmacy and Medicine and Traditional Medicine (DPPMT). The project will be adhering to the MSPP operational plan for management of unusable pharmaceutical products.

The overall project objectives are:

- Remove unusable pharmaceuticals from health facilities to prevent illicit resale.
- Avoid the risks of uncontrolled transfer and destruction of potentially dangerous and hazardous products.
- Protect the environment by complying with the provisions of the framework law on the environment; and
- Avoid returning the expired products to the informal circuit.

Unusable pharmaceuticals are products that have expired, altered, or deteriorated, or products that have been recalled . These products are collected at the level of health institutions supported by the American government or stored at the central warehouse.

Most unusable pharmaceutical products are not a direct source of disease, but their unsafe storage, destruction or improper reuse could have dramatic consequences on the public health of the Haitian population. Some outdated drugs can undergo molecular modifications and chemically degrade to toxic substances, harm public health, contaminate the environment or be “recycled” on the black market. UPP disposal must be done in accordance with international standards and environmental requirements with high temperature incinerators.

The key stakeholders in this project are the Haitian Ministry of Health, the United States Environmental Protection Agency (USEPA), USAID, GHSC-PSM/CHEMONICS. The incineration services would be provided by:

| Institution’s Name | Address |
|---|---|
| Institute of Infectious Diseases and Reproductive Health (IMIS) | Tabarre 41 Entrance Rue T.Auguste, Rue Roumain, Port-au-Prince, Haiti |

To prevent the misuse of UPP diversion to black market or grey market for resale, and/or environmental problems, GHSC-PSM will facilitate its disposal through high temperature incineration and all handling and storage in accordance with applicable international guidelines as follows:

- (a) Upon receipt of the Product Waste, the total amount of waste will be weighed, using an appropriate weighing machine and personal protective equipment, and without opening the storage carton.
- (b) The Product Waste will be recorded and the records maintained.
- (c) After the Product Waste has been recorded, incineration will begin. Any Product Waste not being immediately incinerated will be kept in the incineration room to be processed the next day.
- (d) The incineration will be conducted in accordance with established procedures and any waste generated will be managed consistent with established procedures.

2.1 ACTIVITY WORK PLAN

Unusable pharmaceutical products will be incinerated in Haiti. The project will use the service of Institute of Infectious Diseases and Reproductive Health (IMIS) services to ensure the destruction of the waste products.

2.1.1 Planning

In preparation for this activity, GHSC-PSM field office issued a Request for Quotation on March 14, 2022, for the provision of incineration services and invited the IMIS and the University Hospital of Mirebalais (HUM) to submit proposals. The project only received a proposal from IMIS.

IMIS submitted a patent certificate and a tax number to operate its incinerator.

The service will be paid per kilogram of products and the institution will be providing an incineration certificate for each batch they process.

The Ministry of Public Health and Population (MSPP) will oversee the incineration activity to ensure compliance with the technical specifications defined in the subcontract with the incineration service provider (IMIS) and will certify the destruction of the expired and damaged health commodities and proper management of any waste

generated.

2.1.2 Inventory

The project collects waste products from health facilities and from the Central Warehouse on a monthly basis and stores them at the Tabarre warehouse in Port-au-Prince. The GHSC-PSM project will verify the waste products inventory at the Tabarre warehouse through a physical count. The Waste Management Officer and trained project staff will complete the physical count under the supervision of the Warehouse and Distribution Director

The physical quantity resulting from the inventory exercise will also be verified against the WMS data and it will include the waste products sent to the Tabarre warehouse and the waste products placed at the waste products cage within the Central warehouse.

The waste product sent to the IMIS for incineration will be recorded accordingly in the inventory and included in a POD for delivery at the IMIS location.

2.1.3 Transportation

The waste product will be collected from health facilities monthly. The project will gather the information on quantities to be collected and will use it to define the size and capacity of the vehicles to rent for the collection of waste products.

For small waste product quantities, the project will use 1PL (project vehicles) and for larger quantities GHSC-PSM will subcontract 3PL containerized trucks locked with seals.

The waste product will be collected and transported in their original packaging or packaged in new packaging (cartons) if the original packaging is damaged. The project collects waste products from 272 Health Facilities and will schedule the collection based on availability of waste products at facilities for collection.

The GHSC-PSM subcontracted trucks will follow an itinerary to collect waste products from health facilities where the products will be counted, registered, and loaded. The health facility representative with a GHSC-PSM Waste Management Officer will jointly open the seal of the truck to allow operations and a new seal will be applied at the end of the loading operation at each facility included in the collection itinerary.

The trucks will be driven by the GHSC-PSM subcontracted 3PL driver to the Tabarre warehouse for sorting and bagging and labeling prior to dispatching them to the IMIS. Waste products will be tracked from collection to dispatching them to the IMIS, records verified, and records maintained and made available for inspection.

2.1.4 Sorting and Deconditioning

The GHSC-PSM project will conduct sorting and unpacking of the waste products at the Tabarre warehouse. To do so, the project will use the service of temporary handlers to carry out this work. The products that will be eliminated by incineration are solid products (anti retro viral, antibiotics, anti-inflammatory and analgesic, vaginal ovules, etc.) and semi-solid products (Miconazole creme), powdered forms. Other forms and types of products will be destroyed by solidification such as narcotics, antibiotic vials, vials of laboratory products.

The products will be sorted into five categories and recorded in the Pharmaceutical Waste Tracking Register before deconditioning.

The categories to be distinguished are:

Category 1 - Solid and semi-solid products: tablets, capsules, granules, powders, creams, ointments, gels, suppositories, contaminated packaging, etc.

Category 2 - Liquid products: solutions including solid solutions, liquid emulsions and suspensions, syrups, lotions, etc.

Category 3 - Gaseous or liquefied products: Aerosol cans, including atomizers with propellant and inhalers

Category 4 - Special products at risk, requiring special management conditions:

- ❖ Internationally controlled substances (narcotic drugs and psychotropic drugs).
- ❖ Anti-Neoplastic (or Cytotoxic Anti-cancer), regardless of presentation or form.

Category 5 - Packaging of products and empty packaging (alcohol can, empty bottle of solid solute after use, etc.).

At the time of unpacking, the same product will have more than one expiry date and different lots. When unpacking, these references will be lost, and the warehouse staff will be relabeling them with a product reference number used in the register Excel file.

GHSC-PSM will be transporting the sorted waste products to the IMIS for incineration. The project could use either a 3PL transportation services provider or project vehicles (1PL).

2.1.5 Temporary Storage

Upon arrival to the IMS, the waste products will be placed in the containers GHSC-PSM procured for the MSPP where they will be temporarily stored until the date of incineration.

The containers locks will be managed by IMIS who will be responsible for the physical count and verification of waste products quantities received from the Tabarre warehouse. The GHSC-PSM and an IMIS representative will be countersigning the quantities register.

2.1.6 Treatment

The incineration will follow the MSPP National Operational Plan and the WHO guidelines for disposal and incineration of medical waste. The National Operational Plan states that most of the unusable pharmaceutical products found in Haiti, can be incinerated at 850 °C.

The MSPP's technical specifications for incineration are:

- Incinerator equipped with a secondary combustion chamber
- Temperature greater than 850 °C. even without an air pollution control system, may be suitable for the treatment needs of most waste products resulting from health care activities.
- Rotary combustion chamber incinerator.
- Destruction capacity ranges from 150 kg/h to 500 kg/h.
- Destruction capacity per day is 70 Kg.
- Load capacity of 150 kg or more.

Thus, the GHSC-PSM project and the MSPP through its Directorate of Pharmacy and Medicine and Traditional Medicine identified two health institutions having incinerators that meet the WHO standards and are capable of burning the products at over 850 degrees Celsius. These two institutions are, Institute of Infectious Diseases and Reproductive (IMIS) Health and University Hospital of Mirebalais (HUM). The project will be using the IMIS incineration services.

Incineration Process Description:

Approximately 150 kg of waste products will be destroyed twice a week. On the day of the incineration a GHSC-PSM vehicle will recover 150 kg of waste products from the containers at the IMIS yard and will bring them to the incinerator site. A GHSC-PSM technical representative will be present in the vehicle transporting the waste products within the IMIS facilities.

The incineration plant is designed, equipped, and operated so that the gas resulting from the incineration of hazardous waste is high after the last injection of combustible air, homogeneously controlled and even under the most adverse anticipated conditions, at a temperature of at least 1100°C, for at least two seconds in the presence of at least six per cent (6%) oxygen.

After physical count and verification of quantities, all the stakeholders will check if the required incineration temperatures have been reached before incineration. The incinerator will be fully heated prior to the addition of product waste.

Ongoing monitoring of emissions will be conducted to ensure levels are consistent with international best practices and are consistent with the Haitian Federal Environmental Protection Agency Act. A report on these emissions will be produced at the end of the process.

Ash will be disposed of in an environmentally acceptable manner. The facility operator will visually inspect the ash to determine the rate of combustion due to complete or partial combustion. The operator will wait 30 to 40 minutes until the secondary and primary chamber temperatures are above 1100 and 850 degrees Celsius, respectively. The institution conducting the incineration of waste products will provide an incineration certificate proving the end of the activity (IMIS).

When handling the Product Waste and resulting ash, the following steps will be followed:

- a) Eye protection and a face mask will be worn while opening the loading door or visually checking the unit to protect against glass shards from exploding ampoules and glass bottles.
- b) Heavy-duty gloves and an apron will be worn when handling the Product Waste.
- c) Ash will not be handled by hand.
- d) An adequate cool-down period (3-5 hours) will occur before ash removal.

2.1.7 Disposal

The importance of proper disposal of unusable pharmaceutical products is to avoid that these products are reused in the system and resold on the informal market or that they endanger the environment. The main health risks are summarized below:

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leachate entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage.
- Antineoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, large quantities of disinfectants should not be discharged into a sewerage system or watercourse but can be introduced if well diluted and permitted by environmental permits and under national laws.
- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air. This practice is totally prohibited.
- Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the public. In some countries scavenging in unprotected insecure landfills is a hazard.

- In the absence of suitable disposal sites and qualified personnel to supervise disposal, unwanted pharmaceuticals present no risk provided they are securely stored in dry conditions. If stored in their original packaging, there is a risk of diversion and to avoid this they are best stored in drums with the pharmaceuticals immobilized.

The GHESKIO Institute of Infectious Diseases and Reproductive Health (IMIS) when conducting incineration of waste products for GHSC-PSM will provide:

1. Final weight of waste disposed
2. Incineration certificate signed by the various parties: Institute of Diseases and Reproductive Health (IMIS), University Hospital of Mirebalais (HUM), GHSC-PSM, Ministry of health through its directorate of pharmacy, medicine, and traditional medicine (DPMMT).

After incineration, the residual ash will be packed for collection by the municipality solid waste utility company to be transported and disposed of in the municipal waste field.

2.1.8 Documentation and Filing

The IMIS facility holds a certificate of operation issued by the Ministry of Economy and Finance - General Directorate of Taxes with tax number 000-030-747-7 and patent number 13007028983.

After each batch of waste products has been completely incinerated, an incineration certificate will be issued certifying the waste product destruction. This will be filed as evidence of complete disposal. Copies of the incineration certificate will be sent to GHSC - PSM Home Office.

The template for the incineration certificate was provided by the MSPP through its Directorate of Pharmacy, Medicine and Traditional Medicine. This certificate has two pages; a page listing the products that were destroyed and a page for the following signatures:

- Waste Management Officer and the Inventory Manager of Unusable Pharmaceuticals representing the GHSC-PSM project.
- Pharmacist of the pharmacy branch of the Ministry of Health. (DPMMT representative)
- IMIS' representative and its witness.

During each destruction, two GHSC-PSM staff will be signing the incineration certificate (Annex 2).

The signature of PSM attests that the Project has given in destruction a quantity of product.

The DPMMT will be present at the incineration and will sign this same document attesting that the products have been incinerated.

And the institution responsible for the incineration must also sign this document and must be accompanied by a second person.