REQUEST FOR PROPOSALS (RFP) TGF-D-00014
PHARMACEUTICAL PRODUCTS

Issue Date: 18 March 2022

RFP Closing Date: 10 May 2022

RFP Closing Time: 23.59 hrs. Central European Time (CET)

SECTION 1. LETTER OF INVITATION

Through this Request For Proposals ("**RFP**"), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the "**Global Fund**") invites all potential bidders to submit proposals to supply World Health Organization (WHO) recommended Antimalarial and Antiretroviral Medicines during 2023 to 2025 to, or for the benefit of, recipients of Global Fund financing or other entities, as fully described in this RFP through framework agreements with the Global Fund.

The Global Fund will offer two types of framework agreements that are differentiated by the type of engagement and level of allocation and commitment:

- **Strategic Partnership Agreement:** This type of agreement is expected to be appropriate for suppliers that can demonstrate the ability to supply products throughout their lifecycle and who have the commitment and available resources to work collaboratively in a structured fashion to create value. This category of agreement is expected to include allocated and /or committed volumes on products for which the Global Fund has demand visibility.
- **Purchase Order Agreement:** This category of agreement will establish the framework of the relationship under which selected products will be supplied through individual Purchase Orders as needed, under certain conditions such as when a Strategic Partnership Agreement Supplier is unable to meet the demand request, including when there are intellectual property restrictions. This category of agreement will not include allocated or committed volumes.

The preference for the type of framework agreement can be selected by the bidder at the time of submission. The Request for Proposals includes the following documents:

SECTION 1	LETTER OF INVITATION
SECTION 2	DEFINITIONS
SECTION 3	INSTRUCTIONS TO BIDDERS
SECTION 4	REQUIREMENTS AND TECHNICAL SPECIFICATIONS
SECTION 5	LEGAL MATTERS

SCHEDULE A	Officer's Certificate of Conformance and Acknowledgment
SCHEDULE B	Confidentiality Agreement (if requested by the bidder)
SCHEDULE C	Draft of Framework Agreement between the Global Fund and Suppliers • **C1:** Strategic Partnership Agreement • **C2:** Purchase Order Agreement
SCHEDULE D	Product segmentation
SCHEDULE E	Response Templates • **E1:** Technical (Excel File) • **E2:** Commercial (Excel File)
SCHEDULE F	Demand forecast for Pharmaceuticals (ARVs and ANTM)
SCHEDULE G	List of Panel Pharmaceuticals Manufacturers (issued under certain conditions)
SCHEDULE H	Integrity Due Diligence (IDD) questionnaire

Your proposal, comprising of the Technical, Commercial and For Information and Implementation responses should be submitted in accordance with Section 3.

Should you require any clarification, kindly communicate only through the communication channels identified in Section 3.E.3.

SECTION 2. DEFINITIONS

1. **ACT**: artemisinin-based combination therapies.
2. **Allocated volume (or volume allocation):** Volume of Pharmaceuticals allocated by the Global Fund to the FPP Panel Supplier for manufacture at the agreed price(s) but for which there is no underwritten financial commitment.
3. **Antimalarial Medicines (ANTM)**: World Health Organization (WHO)-recommended medicines for treating and preventing malaria.
4. **Antiretroviral Medicines (ARVs)**: World Health Organization (WHO)-recommended medicines to supress the HIV virus and stop the progression of HIV disease.
5. **API:** Active Pharmaceutical Ingredient
6. **Artemisinin manufacturers:** Manufacturers that produce artemisinin. This includes both extractors and semi-synthetic manufacturers.
7. **Base price:** Price of the product to be offered to the Global Fund through a framework agreement.
8. **Bidder**: Supplier who submits a proposal by the deadline for this RFP.
9. **Committed volume (or volume commitment):** Volume of Pharmaceuticals that the Global Fund undertakes to underwrite financially through a fully executed "Strategic Partnership Agreement" (Schedule C1 of RFP), and for which the FPP Panel Supplier agrees to provide to Committed Volume Buyers, during the period and at the prices specified in the Strategic Partnership Agreement.
10. **Committed Volume Buyer:** Any party which makes a purchase of Pharmaceuticals pursuant to the terms of a fully executed Strategic Partnership Agreement (Schedule C1 of RFP) and as a draw-down of the Committed Volume under the Strategic Partnership Agreement. As of the date of the launch of this RFP, the Committed Volume Buyers are the Procurement Services Agent for the Global Fund and the Pan American Health Organization (PAHO); however, the Strategic Partnership Agreement will specify that the Global Fund may designate additional Committed Volume Buyer(s) during the term of the Strategic Partnership Agreement, by written notice to the FPP Panel Supplier.
11. **Environmental Health and Safety (EHS) Audit:** An audit of Artemisinin manufacturers addressing issues related to environmental health and safety considerations conducted by Finished Pharmaceutical Product manufacturers.
12. **Finished Pharmaceutical Product (FPP) manufacturers:** Manufacturers of a medicine presented in its finished dosage form.
13. **FPP Panel Supplier**: An FPP manufacturer who has been awarded a Strategic Partnership Agreement by the Global Fund for the supply of Pharmaceuticals. The outcome of this RFP will establish the FPP Panel Suppliers for Pharmaceuticals.
14. **Global Fund:** The Global Fund to Fight AIDS, Tuberculosis and Malaria. More information is available here: http://www.theglobalfund.org/en/
15. **HIV:** Human immunodeficiency virus
16. **KSM:** Key Starting Material

17. **Manufacturer Promised Date:** Date by which the FPP Panel Supplier promises to fulfil the Incoterms of the Purchase Order, including providing all the necessary export documentation for the Purchase Order.

18. **National Drug Regulatory Authority:** the official drug regulatory authority of a country

19. **Other selected medicines used in HIV programs:** as identified in Schedule D

20. **OTIF:** On time in full delivery. Further information is provided in Schedule C.

21. **Pan-America Health Organization (PAHO):** which also serves as the Regional Office for the Americas of the World Health Organization, is an international public health agency whose mission is to lead strategic collaborative efforts among its Member States and other partners to improve health and quality of life in the Region of the Americas. PAHO is a Committed Volume Buyer for ARV and other selected medicines used in HIV programmes under this RFP.

22. **Panel Artemisinin Manufacturer**: An Artemisinin manufacturer eligible to supply artemisinin for artemisinin-containing products to be supplied through Global Fund Strategic Partnership; the list of Panel Artemisinin Manufacturers is conditionally provided in Schedule G.

23. **Pooled Procurement Mechanism (PPM):** Program managed by the Global Fund that aggregates order volumes on behalf of participating Principal Recipients of Global Fund grant funding in order to negotiate best prices and delivery conditions with FPP Panel Suppliers and other suppliers. More information is available at: https://www.theglobalfund.org/en/sourcing-management/health-products/.

24. **Pharmaceuticals:** Antimalarial, Antiretroviral and other selected medicines used in HIV programs

25. **Principal Recipient (PR):** Entity nominated to implement a program designed to utilize Global Fund grant funds to fight against the diseases of HIV/AIDS, tuberculosis and/or malaria, including strengthening of related health systems, in a country.

26. **Private Sector Co-payment Mechanism (CPM):** Program managed by the Global Fund to increase access to quality-assured artemisinin-based combination therapies through private sector distribution channels in participating countries. This is a follow-on program to the Affordable Medicines Facility-malaria (AMFm). More information is available here: https://www.theglobalfund.org/en/sourcing-management/procurement-tools/#co-payment-mechanism

27. **Procurement Services Agent (PSA):** A Procurement Services Agent selected by the Global Fund to act as an agent on behalf of Principal Recipients in the procurement of, among other items, Pharmaceuticals through the Pooled Procurement Mechanism. The current PSA for Pharmaceuticals is Stichting Iplussolutions. The PSA is subject to change at any time.

28. **Procurement Strategy:** The Global Fund's Procurement Strategy for Pharmaceutical Products 2022-2025.

29. **Rapid Supply Mechanism:** The Global Fund's process at enabling the fulfilment of orders to meet emergency or unexpected demand across its whole grant portfolio including non-PPM procurement channels.

30. **Related Firm:** Any legal person or undertaking who controls or is controlled by another legal person or undertaking, or where two or more legal persons or undertakings are under common control. "Control" is defined as the power to exercise a direct or indirect decisive influence over the management or policies of a firm, including its commercial strategy, whether through the ownership of voting securities, by contract, or otherwise. Any person

who owns beneficially, either directly or through one or more controlled firms, more than 25 percent of the voting securities of any firm is presumed to control the firm.

31. **SSA**: Semi-Synthetic Artemisinin
32. **Semi-synthetic manufacturers:** Manufacturers that use fermentation and other synthetic processes to produce artemisinin.
33. **Standardized labelling:** FPP labelling without country-specific customization.
34. **Stringent Drug Regulatory Authority (SRA):** A regulatory authority which is (a) a member of the ICH [membership as before 23 October 2015]; or (b) an ICH Observer (as before 23 October 2015), being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as before 23 October 2015) (as may be updated from time to time)
35. **Total Landed Cost:** Total cost of a landed shipment including purchase price, freight, insurance and other costs up to the point of delivery.

SECTION 3. INSTRUCTIONS TO BIDDERS

A. CONDITIONS FOR PARTICIPATION

1. Bidders must advise whether their company intends to submit a proposal by clicking on the "Yes" or "No" button which will be at the end of the email you will receive through our TGF Sourcing Application before the deadline mentioned in Section 3B: Timeline.

2. Only bidders with products in compliance with the Global Fund Quality Assurance Policy for Pharmaceutical Products (2010, as amended from time to time) are eligible to participate in this RFP as a Bidder (see https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/), and all products supplied pursuant to this RFP must comply with those requirements.

3. Submitting a proposal in response to this RFP constitutes an acceptance of the terms indicated herein, including the terms and conditions set forth in Section 5 "Legal Matters", and of the terms of each of the documents referred to in this RFP. The Global Fund reserves the right to reject the proposal of any entity or individual, as the case may be, that fails or refuses to comply with, or accept, such terms. Schedule A shall be signed and submitted by all Bidders as part of their proposal.

4. Bidders must comply with the Global Fund's Code of Conduct for Suppliers and shall be subject to the Global Fund's Sanctions Procedures Relating to the Code of Conduct for Suppliers. Submitting a proposal constitutes an acknowledgement that the Global Fund will conduct appropriate due diligence to obtain assurance of the bidders' track record, capacity and willingness to comply with the Code of Conduct for Suppliers.

5. Related Firms are not allowed to submit separate proposals and are required to determine among themselves which firm is the best suited to submit a proposal or submit a consolidated single proposal as a consortium.

6. If Related Firms wish to participate in the tender as a consortium, the firm representing the consortium shall be authorized to submit the proposal on behalf of each consortium member. Although the Global Fund may enter into direct contracts with each of the consortium members, the consortium will be evaluated as a whole for the purpose of the tender evaluation and during contract implementation, and if the offered products are subject to allocation will receive an allocation to be shared among consortium members. All Related Firms, as consortium members, shall submit and sign separate Schedules A and E. One Schedule H questionnaire shall be completed for a consortium, explaining the structure and how ownership and control will work. The consortium shall offer a single price for the same product that can be provided by two or more consortium members. The allocation and volume commitment, if applicable, will be made to the consortium, which entails that if one consortium member cannot deliver the desired products, the Global Fund will require the other consortium members to deliver such products to the extent these consortium members supply the said products. By submitting a proposal in response to this RFP the consortium, and all consortium members, agree to the rules and conditions outlined in this Section.

7. Non Related Firms are not allowed to form a consortium and submit a consortium proposal.

8. All proposals must remain valid until December 31, 2022.

9. A bid security is not required for proposals submitted under this RFP.

10. A bid bond is not required for proposals submitted under this RFP.

11. Bidders are not required to quote for all products. However, Bidders are encouraged to quote for as many products as possible.

B. TIMELINE

1. Proposals must be submitted by the deadline shown below. The scheduled time of the key activities of this RFP are as follows, with all times Central European Time (CET):

	Scheduled Deadline
1. Request for Proposals issued	March 18, 2022
2. Deadline for prospective bidders to submit clarification questions through the "Message Function" on the Sourcing Application to the RFP – Round 1	March 24, 2022 17:00 CET
3. The Global Fund to issue responses to clarification questions to all prospective bidders – Round 1	March 29, 2022
4. Deadline for prospective bidders to submit clarification questions through the "Message Function" on the Sourcing Application to the RFP – Round 2	April 15 , 2022 17:00 CET
5. The Global Fund to issue responses to clarification questions to all prospective bidders – Round 2	April 19 , 2022
6. Deadline for electronic submission of proposal (close of RFP)	May 10, 2022 23:59 CET
7. Notification of Stage 2 (if needed)	The week of June 6, 2022
8. Tentative dates for Stage 2 (if needed)	June 21, 2022
9. Notification of Awards to Bidders	September 7, 2022

2. The Global Fund reserves the right to modify the timeline at any time. In such a case the Global Fund will inform all potential bidders, but it is the responsibility of potential bidders to regularly check the relevant Global Fund's procurement pages on its website.

C. CONTENTS OF PROPOSAL

1. Overall Process

   a. The Global Fund may not consider any proposal that is received by the Global Fund after the indicated deadline for electronic submission of proposals. Any proposal received by the Global Fund after the indicated deadline for electronic submission of proposals will be declared late and may be rejected.

   b. The selection and evaluation process will be conducted in line with the procurement principles of the Global Fund's Procurement Policy (2008, as amended from time to time), and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2021, as amended from time to time) (https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf).

   c. During the evaluation of proposals, the following definitions apply:

      1. "Deviation" is a departure from the requirements specified in this RFP;
      2. "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in this RFP; and
      3. "Omission" is the failure to submit part or all of the information or documentation required in this RFP.

2. Confidentiality and Integrity

   a. Information relating to the contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until information on contract award is communicated to all Bidders. Information relating to the evaluation of proposals shall not be disclosed to Bidders.

   b. Any attempt by a Bidder to influence the Global Fund in the evaluation of proposals or contract award decisions shall result in the rejection of its proposal.

   c. The Global Fund also recognizes that some of the information requested is commercially sensitive and, at a bidder's request, will execute a confidentiality agreement in the form attached as Schedule B.

D. PREPARATION OF THE PROPOSAL

1. Bidders are required to complete and submit the following Schedules and response templates:

Response	**Strategic Partnership Agreement and Purchase Order Agreement[1]**	**Submission Format**
Schedule A	Officer Certificate of Conformance and Acknowledgement	Signed PDF
Schedule B	Confidentiality Agreement (if requested by the Bidder) - Optional	Signed PDF
Schedule E	E1: Technical Proposal E2: Commercial Proposal	Excel + signed PDF

[1] See Section 1 for description of Purchase Order Agreement

TGF Soucing Application	For Information and Implementation Proposal	Not Applicable
Schedule H	Integrity Due Diligence (IDD) questionnaire	Word + Signed PDF

2. Bidders who wish to offer products from more than one manufacturing site located in different countries shall complete separate Schedule E templates for each manufacturing site. (All Related Firms taking part in a consortium shall also complete separate Schedule E templates (see Sections 3A5 to 3A7)).

3. Bidders are expected to fully respond to all questions and provide relevant information as required. Failure to do so will be considered incomplete responsiveness and will be taken into account in the overall evaluation.

4. All Bidders must also complete and sign the Officer's Certificate of Conformance and Acknowledgement at Schedule A which confirms their compliance with the requirements of the proposal and conditions of supply. Non-conforming proposals will not be eligible for the evaluation process. Bidders are expected to accept Global Fund's terms and conditions as set forth in the Strategic Partnership Agreement or Purchase Order Agreement (Schedule C). Only reservations or requests for amendments to the Strategic Partnership Agreement or Purchase Order Agreement submitted by Bidders as part of their proposal may be considered by the Global Fund. These reservations or requests for amendment will be taken into account in the overall evaluation. The Global Fund has no obligation to agree to these reservations or requests for amendment.

5. All proposals must conform to the following conditions:

   a. Must be submitted in English
   b. Pricing must be in US Dollars
   c. Prices must be the price of goods EXW as defined in INCOTERMS 2020 published by the International Chamber of Commerce.

E. SUBMISSION OF THE PROPOSAL

1. This RFP process is being managed electronically, and Bidders are required to submit their proposals and any questions through the TGF Sourcing Application in the following URL: https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/.

2. **In case you do not have a Supplier ID for the TGF Sourcing Application,** please send an email in advance to strategicsourcing.support@theglobalfund.org with the following title in the subject: Request for login user id creation in TGF Sourcing/iSupplier portal – "Organizations name".

3. Once in possession of a Supplier ID, all communication must be channeled through the TGF Sourcing Application: https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/. Only in exceptional circumstances, such as technical difficulties in accessing the platform, can communication be made by email – in which case, any communication must indicate in the subject line of the e-mail the company name and the RFP number (TGF-D-00014) and be addressed to the following email address: strategicsourcing.support@theglobalfund.org

4. Any communication between a Bidder and the Global Fund regarding this RFP which is not through the channels designated above may invalidate such Bidder's proposal to this RFP.

5. All proposals are to be submitted through the TGF Sourcing Application, including the three pre-formatted templates for Schedule E (i.e., Schedule E1, Schedule E2, and Schedule E3). Each proposal Schedule is to be submitted as a separate file with each file not exceeding 8 mb.

F. EVALUATION OF THE PROPOSAL

1. After the deadline for electronic submission of proposals, the Global Fund will examine the proposals to determine whether they are substantially complete, whether the documents have been properly signed and whether the proposals are generally in order. Any proposal found to be unsigned or signed by an unauthorized person, not meeting the minimum requirements in this RFP, or not providing the minimum information that is essential for the evaluation of the proposals, may be rejected by the Global Fund and not included for further consideration.

2. Following the initial evaluation and assessment, the Global Fund will review the initial submissions and determine whether it considers additional value could be obtained by engaging with selected Bidders for a Stage 2 process. Only if a Stage 2 process will be undertaken, by the date indicated in Section 3B, an amendment to the RFP will be posted with the specific details related to any Stage 2 process.

3. Bidders expressing a preference for a Strategic Partnership Agreement will be evaluated as described below. Bidders expressing a preference for a Purchase Order Agreement are required to provide the same information for contracting purposes, which may be evaluated.

4. In keeping with the range of strategic objectives, the RFP evaluation will be based on multiple evaluation criteria of both commercial and non-commercial nature. The selection and evaluation process will be conducted pursuant to the Global Fund's procurement rules, regulations, and procedures. The following principles underpin the evaluation process and should be fully understood by Bidders:

    a. Any material deviation, reservation or omission from any of the required elements and criteria will be considered in the selection process by the Global Fund even if that element is required for information only.

    b. Proposals will be evaluated against technical and commercial elements, within which certain criteria will be evaluated. Scoring mechanisms and the contribution of individual criteria within each element will be the same for each Bidder.

    c. Each technical and commercial element is linked to the Global Fund's "Balanced Supply System" principles and based on key objectives of the The Procurement Strategy, as described in Section 4.

5. Technical and Commercial Evaluation: Proposals will be evaluated against the criteria defined, and Bidders will be ranked in order of evaluated scores, using a normalization algorithm to score Bidders relative to each other. The scores will then inform the first year of allocation, if any.

6. The overall weighting of the Technical and Commercial Evaluation will be:
    a) Technical: 55%
    b) Commercial: 45%

7. For Schedule E, the following information is required:

Schedule E1: Technical Template

Elements	Information Type
1. Product coverage and Quality Assurance Policy Regulatory Status – WHO Prequalification / Stringent Regulatory Authority	Evaluated information
2. Country registration approval coverage	Evaluated information
3. Supply security and visibility	Evaluated information
4. Projects to deliver on strategic objectives	Evaluated information
5. Africa Footprint: proximity to high volume demand	Evaluated information
6. On time in full delivery	Evaluated information

Schedule E2: Commercial Template

Elements	Information Type
1. Base Price and Total Landed Cost – Price 2023	Evaluated information
2. Base Price and Total Landed Cost – Price 2024 & 2025	Required information*
3. Advanced Purchase Order discount	Required information*
4. Cost breakdown	Evaluated information

TGF Sourcing Application For Information and Implementation

Elements	Information Type
1. Company information	Required information*
2. GS1 bar coding standard	Required information*
3. Carton-Less packaging for ARV second line regimen	Required information*
4. Labelling for ARV and ANTM	Required information*
5. Rapid Supply Chain (RSM) Mechanism	Required information*

*Required information may be validated

8. In addition to clarifications provided in Schedule E, a description of each of the elements of requested information is provided below.

9. **Schedule E1:** Technical Template

   a) ***Product coverage****:* Clarification of the Pharmaceuticals that are eligible for submission and evaluation:

   - Section A, column F to P: Approved Finished Pharmaceutical Products compliant with Global Fund's Quality Assurance Policy for Pharmaceutical Products (https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf) and which will be offered by the Bidder. For each eligible product offered, information on regulatory status is to be specified: regulatory reference number, approval date and approved shelf life;

   - Finished Pharmaceutical Products not compliant with the Global Fund's Quality Assurance Policy but submitted and accepted for review by the WHO Prequalification Programme, a Stringent Drug Regulatory Authority or the Global Fund's Expert Review Panel should be reported under Pipeline Product in column V and W of the Schedule E1.1_Product Coverage. A proof of submission has to be submitted;

   - Section B, Innovative Products. For any product listed under the scope of Innovative Product please filled in the required information together with supporting document;

   b) ***Country coverage****:* Clarification of the countries in which the Bidder has received its approval for use for each offered product by the National Drug Regulatory Authority. Bidders are requested to submit, for each offered product, the registration status of each PPM country, including the authorization number, approval date, expiry date, long life validity, annual retention and the retention paid date. The list of PPM countries is specific to each category and is listed in Schedule E1.2 Country Coverage.

   c) ***Supply Security and Visibility:***

   - *Clarification of internal and external API sources, Key Starting Materials, Artemisinin sources and qualification of SSA in the current approved FPP dossier. The objective is to evaluate the number of API and KSM sources each Bidder relies on as well as their geographical diversification and to strengthen the uptake of SSA.*

   - *Management of implementation of Global Fund Antimalarial Medicines Strategy related to artemisinin supply (for artemisinin-containing products):* Bidders are requested to describe their business relationships with Panel Artemisinin Manufacturers and/or active pharmaceutical ingredient (API) suppliers to ensure good business practices across the product supply chain. For each Panel Artemisinin Manufacturer in the Bidder's supply chain (whether direct or indirect through an API supplier for products that contain artemisinin), describe the contract duration, the allocation of volume (as a percentage) across Panel Artemisinin Manufacturers and the FOB Incoterm Price (in USD/kg) as well as whether artemisinin is purchased from an API manufacturer.

   - *Use of SSA (for artemisinin-containing products):* To indicate whether you have qualified *SSA* as a source and describe any agreements with semi-synthetic manufacturers. SSA *has not been yet qualified,* describe the reason and the timeline to start using SSA.

d) ***Projects to deliver on strategic objectives:*** The Global Fund has a broad definition of value that is articulated in its Market Shaping Strategy; this and how it is applied to products under RFP scope is described in Section 4 of this RFP. The Global Fund is interested in receiving a limited number of feasible proposals from each Bidder on delivering measurable outcome in line with the Procurement Strategy objectives as detailed in Section 4B. The evaluation of this element will assess the overall value/impact of the project as well as an assessment of feasibility and ability to deliver the proposed outcomes. Whilst the Schedule contains a basic outline, additional details should be provided separately to fully articulate the proposal. Priority areas of interest to the Global Fund include, but are not limited to:

i. Achieving manufacturing, packaging and labelling efficiencies (except for carton-less ARV 1st and 2nd line regimen)

ii. Achieving **shorter lead-times** through innovative manufacturing, storage or other supply chain solutions (excluding **the Rapid Supply Mechanism)**

iii. **Africa Footprint:** Bidders with a defined project aimed at developing a manufacturing/packaging and/or a distribution center in Africa which will be deployed during the implementation period (prior to end 2025). Selected suppliers will be expected to provide supporting documents and substantial evidence at the time of submission, and during implementation on progress and timelines. The sole intention or idea will not be considered.

The Global Fund reserves the right to request revised or additional proposals from all or some Bidders as part of the Stage 2 process.

e) ***Africa footprint: proximity to high volume demand.*** Bidders are required to indicate whether they fully or partially perform any stages of API production, manufacturing, packaging and/or distribution center at sites in Africa compliant with the Global Fund's Quality Assurance policy.

If Bidders perform any activities in Africa, Bidders are required to indicate for each item impacted the percentage of the total quantity of finished pharmaceutical product(s) that will be supplied to the Global Fund from these sites.

For example, a response might specify that:

- 40% of the total quantity of finished pharmaceutical products X and Y, to be supplied through Strategic Partnership Agreements will come from a manufacturing site in Africa where products have undergone all stages of production.

- 10% of the total quantity of finished pharmaceutical product, Z, will come from a manufacturing site in Africa where bulk products are finally packaged and labelled

- 50% of the total quantity of finished pharmaceutical products will come from manufacturing sites outside of Africa.

During implementation, the Global Fund will monitor if the products are coming from the sources indicated and the extent to which the percentage split as described in the proposal submission is met, as specified in the Strategic Partnership Agreement (Schedule C1 of RFP).

f) ***On time in full delivery (OTIF)*** *(based on historical internal data, for all products supplied through Global Fund Framework Agreements in calendar years 2018-2021 inclusive):* On time in full delivery data to be evaluated includes data previously verified during quarterly performance reviews with FPP Panel Suppliers that have Framework Agreements

with the Global Fund in effect at present. PPM OTIF refers to the percentage of purchase orders with shipment delivery dates not exceeding the Manufacturer Promised Date by more than 7 days out of the total number of purchase orders. Bidders with no delivery history through Global Fund Framework Agreements will not be disadvantaged in the evaluation.

10. **Schedule E2: Commercial Template**

Bidders who wish to offer products from more than one manufacturing site located in different countries and at a different base price shall complete a separate Schedule E2 template for each site.

(1). ***Base Price and Total Landed Cost*** *(price for 2023):* Bidders will submit information on prices offered per product in USD (EXW price) to the nearest cent. The Global Fund will determine the Total Landed Cost, based on market freight cost data.

The price per individual- level treatment dose of ACTs to be supplied through CPM will be calculated based on the price submitted in Schedule E2, divided by the number of blister/strip per pack, and will be rounded to the nearest cent.

(2). ***Base Price and Total Landed Cost*** *(price for 2024 & 2025):* Anticipated prices for 2024 and 2025 are requested for information only and will not be evaluated.

(3). ***Advanced Purchase Order discount*** *(i.e., for Purchase Orders placed and confirmed more than 10 weeks before Manufacturer Promised Delivery Date):* Discounted price (to the nearest cent), if any, for any purchase order placed and confirmed more than 10 weeks before the Manufacturer Promised Delivery Date.

(4). ***Cost breakdown*** *(in the separate tab provided in the Schedule):* Bidders are required to describe the various cost elements requested. Bidders are requested to complete information for API 1 and onwards in the columns provided.

For artemisinin-containing products *Bidders are required to indicate the* average artemisinin conversion ratio (1 kg respective API: Artemisinin kg) and cost of processing (in US$/kg respective API)

11. **TGF Sourcing Application For Information and Implementation**

(1). ***Company information:*** Information relating to the legal name, type, form of organization, country of registration, whether part of a related group (and if so, the controlling entity).

(2). ***GS1 bar coding standards: Bidders*** are requested to respond to the questions related to GS1 bar coding standards.

(3). ***Carton-Less packaging for ARV second line regimen****: Bidders are requested to indicate for each item listed if carton-less packaging is offered. If carton-less is not offered, describe the timeline to implement.*

(4). ***Labelling:*** Bidders are requested to respond to the questions related to labelling

(5). ***Interest in contributing to a Rapid Supply Mechanism through Vendor Managed Inventory****:* The Global Fund is strengthening its Rapid Supply Mechanism. Bidders are requested to describe whether they are willing to make available one twelfth of their annual allocated volume (or another volume to be specified by the Bidder) for pick up within 14 days after purchase order placement for the products specified; this mechanism will not apply to products to be supplied through the Co-payment Mechanism.

12. **Stage 2 process, if required**

1. The Global Fund will review the results from the submissions and determine whether it considers additional value could be obtained by engaging with selected Bidders for a Stage 2 process. As there is no certainty Stage 2 will be organized, Bidders are encouraged to submit strong proposals with complete required information and Best and Final Offer (BAFO) during Stage 1.

2. Only if a Stage 2 process will be held, Bidders will be notified through an amendment to this RFP which will be posted with additional details by the date indicated in Section 3B.

G. NOTIFICATION AND CONTRACTING

1. The final decision on contract award, and allocated and committed volumes if any, will be made by the Global Fund and communicated to all selected Bidders by the date detailed in Section 3B. These final decisions will be based on the evaluation approach as detailed in Section 3 of this RFP and the forecasted demand. Any agreement between the Global Fund and a selected Bidder shall be reflected in the terms and conditions of a Strategic Partnership Agreement or Purchase Order Agreement with such Bidder.

2. Unsuccessful Bidders will, in addition to the notification, be provided with an opportunity for a post proposal de-brief either in person or by teleconference. This opportunity to de-brief shall not create any legal rights, including without limitation any right of appeal.

3. A final qualification with any proposed FPP Panel Supplier is subject to the signature of the Strategic Partnership Agreement. If a proposed FPP Panel Supplier does not sign a Strategic Partnership Agreement, the Global Fund will take appropriate action at its discretion, including, without limitation, removal or suspension from the panel.

SECTION 4. REQUIREMENTS & TECHNICAL SPECIFICATIONS

A. BACKGROUND

1. The core objectives of the Global Fund 2023-2028 Strategy, ***Fighting Pandemics and Building a Healthier and More Equitable World***, available at https://www.theglobalfund.org/en/strategy/ are to: Maximize people-centered integrated systems for health to deliver impact, resilience and sustainability; maximize the engagement and leadership of most affected communities to leave no one behind; maximize health equity, gender equality and human rights; and mobilize increased resources.

2. In support of the 1st Strategic Objective of the Global Fund 2023-2028 Strategy, Maximize people-centered integrated systems for health to deliver impact, a key mutually reinforcing contributary links directly with the Global Fund's Next Gen Market Shaping Strategy:

    a. NextGen market shaping focus on equitable access to quality health products through innovation, partnership, and promoting sustainable sourcing and supply chains at global, national and community levels.

3. The Next Gen Market Shaping Strategy will replace the current Global Fund Market Shaping Strategy (https://www.theglobalfund.org/en/sourcing-management/market-shaping-strategy/) once it expires at the end of 2022.

    Building on our successful market shaping efforts to date, the Next Gen Market Shaping shaping approach will entail a greater end-to-end focus on integrated upstream, midstream, and downstream activities, with the aim of delivering quality, innovative health products and services more inclusively, efficiently, and sustainably, as well as enabling more effective introduction and scale-up of innovations that can impact the trajectory to end the three diseases and contribute to the achievement of the United Nations' Sustainable Development Goal 3.

    Guiding the Next Gen Market Shaping efforts are the following objectives:

    - Leverage the Global Fund's market shaping power by harnessing and scaling synergies across the portfolio.
    - Facilitate equitable, sustainable access to quality health products and services.
    - Foster innovation through partnerships by connecting industry, in-country procurement decision-makers, communities, academia, development and other partners.
    - Champion environmentally sustainable sourcing and supply.

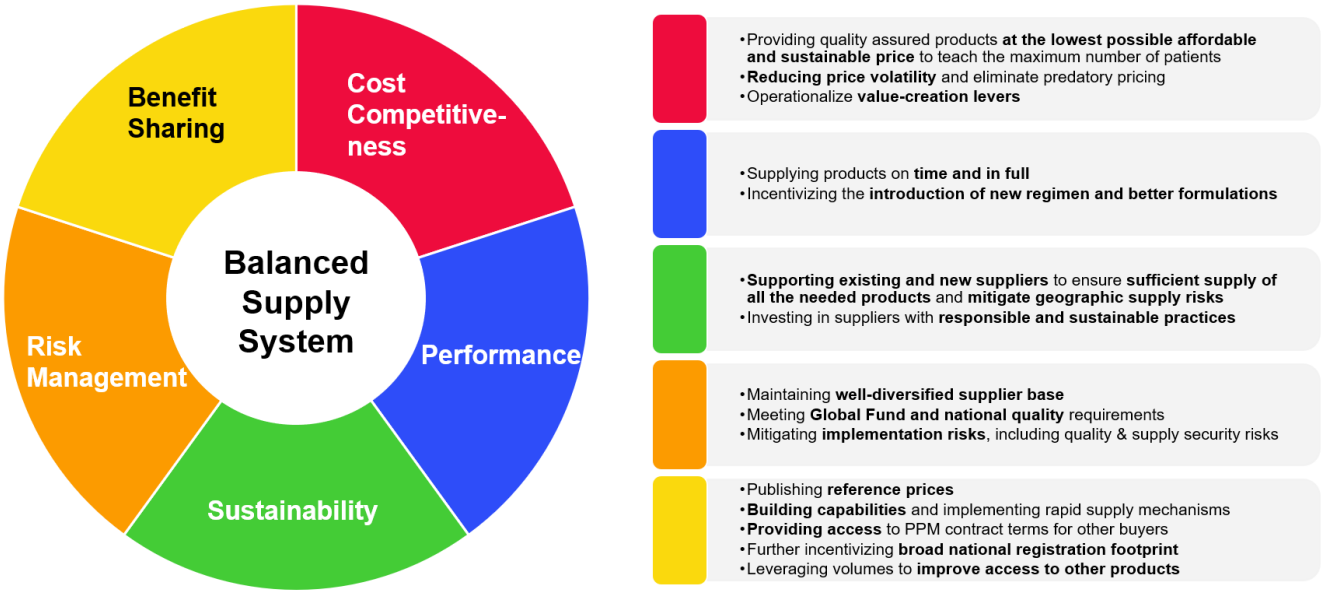
Figure 1. Next Gen Market Shaping Framework



4. The Global Fund's Supply Operations Department implements the Market Shaping Strategy and will implement the Next Gen Market Shaping by managing health products through the Pooled Procurement Mechanism along five key dimensions:
    a. Pooled demand: Registering Principal Recipients into the mechanism creates the opportunity to pool volumes of large and small volume countries.
    b. Product category strategies: Designing, issuing and managing sourcing strategies, including competitive tenders to support category-specific market shaping objectives.
    c. Supplier relationship management: Managing the implementation of long-term agreements including the allocation and performance management of suppliers.
    d. Demand management: Optimizing resources to manage Principal Recipient demand along three dimensions: volume, time and specification.
    e. Transaction management: Executing PPM orders from requests to deliveries via wambo.org, a PR-facing portal that increases visibility of ordering operations with full visibility and a transparent auditable process.

5. In support of achievement of its market shaping objectives for any product category, the Global Fund values a balanced supply system based on five elements to encourage strong supplier performance from a robust supplier base, as described in Figure 2 below.

Figure 2. Balanced supply system to support strong supplier performance



6. The Global Fund's Procurement Strategy for Pharmaceuticals, described on the Global Fund website, available at https://www.theglobalfund.org/en/sourcing-management/health-products/, and of which this RFP is a core element, supports the achievement of the Global Fund's market shaping objectives and builds on the experience and lessons learned from the previous Procurement Strategies for Antiretroviral and Antimalarial Medicines.

The Procurement Strategy is based on a combination of analysis of recent market dynamics data and discussions with manufacturers, grant recipients, donors, key partners and other technical agencies.

For the avoidance of doubt where any presentation documentation of the RFP or the Global Fund's Procurement Strategy and this RFP differ, this RFP shall prevail.

B. OBJECTIVES

1. The purpose of this RFP is to select FPP Panel Suppliers who will enter into Strategic Partnership Agreements with the Global Fund, as well as other suppliers supplying pharmaceutical products under Purchase Order Agreements, to implement its Procurement Strategy and to supply WHO-recommended Pharmaceuticals procured with Global Fund financing through the Pooled Procurement Mechanism.
2. These agreements will be for a three years term from 2023 end-2025. Strategic Partnership Agreements may comprise allocated and committed volumes, depending on the products to be supplied, determined at the time of Strategic Partnership Agreement signature for 2023 and each following calendar year's volumes are expected to be established in the first quarter after consideration of the annual performance of the prior period. For the avoidance of doubt, allocated volumes shall not be legally binding unless expressly and unconditionally stipulated as such in a duly executed Strategic Partnership Agreement.
3. The aim of the Procurement Strategy for Pharmaceutical Products 2023-2025 , which is a procurement strategy for both antiretroviral and antimalarial medicines, is to increase access to all needed WHO-recommended Pharmaceuticals at the optimum price whilst simultaneously maintaining a competitive market (details are available at: https://www.theglobalfund.org/en/sourcing-management/health-products/antimalarial-medicines/ and https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/)
4. Detailed objectives of the Procurement Strategy to support this aim fall into the following categories and are described in further detail below: competitive & sustainable pricing, supply chain security, innovation & sustainable procurement, Supplier Relationship Management aligned with SMART partnerships, and quality assurance.
    a. **Competitive & Sustainable Pricing to deliver health product availability and affordability;** creating value beyond product pricing.

    General sub-objectives:

    i. Maintaining and supporting the competitive and sustainable markets
    ii. Controlling costs to ensure the optimal use of resources
    iii. Broadening the definition of "Value" beyond pricing
    iv. Encouraging the investigation of savings opportunities beyond product costs
    v. Maintain multi-year agreements to support the achievement of these strategic objectives.
    vi. Continue the RSM process with the aim to reduce lead times further

vii. Increase supplier accountability, including via Most Favoured Nation implementation

Artemisinin-specific sub-objectives:

i. Building on artemisinin strategy successes; securing access & strengthening the uptake of SSA remains a key element of the strategy

ii. Broadening artemisinin access; allowing the introduction of new suppliers but with increased supplier accountability for ensuring EHS compliance & conformity

iii. Requirement for all suppliers to have a SSA supplier approval

iv. Encouraging suppliers to uptake a minimum of SSA annually

b. **Supply Chain Security for responsive and agile health services and product delivery;** a stronger focus on supplier accountability and supply chain robustness.

i. Securing a continuous, reliable supplier of all required ARV and ANTM medicines

ii. Focusing on supplier accountability to ensure upstream supply security and supply chain robustness

iii. Maintaining a resilient supply base to ensure reliable and sufficient supply of health products

iv. Promoting geographic manufacturing diversification, local manufacturing and local capacity building

v. Improving product traceability through market surveillance for quality and access; allowing for accurate product and quality incidents tracking throughout the supply chain.

vi. Carrying on GS1 barcoding standards implementation

vii. Moving towards a make-to-stock model to mitigate supply fluctuations

viii. Deepening partnership with suppliers to proactively understand and address supply challenges.

ix. Improving demand management, a key driver of overall supply performance

x. Encouraging more responsive supply by maintaining the Rapid Supply Mechanism to respond to stock-out risks

c. **Innovation to accelerate new product introduction at scale and to drive environmentally sustainable procurement and supply chains;** ensuring patient access to optimal formulations, prices and reducing environmental impact.

i. Supporting a robust pipeline of new products intending to improve efficacy, reduce costs, and better meet the needs of end users in line with disease guidelines

ii. Continuing to stimulate innovation through agreed supplier-driven projects

iii. Improving on new product uptake & accelerating the transition to more optimal health products

iv. Leveraging innovations which reduce packaging and shipping costs

v. Reducing environmental and carbon footprints through (eg.) better product and logistical planning, optimizing and adapting transport routes, reducing packaging etc.

vi. Focusing on supplier accountability to ensure upstream supply security and supply chain robustness

vii. Promote responsible procurement, including good business practices, throughout the supply chain

d. **Supplier relationship management (SRM), aligned with a SMART (Specific, Measurable, Achievable, Realistic, and Timely) partnership approach;** strengthening partnerships and accountabilities.

i. Continuing to strengthen performance management through quarterly reviews with an increased emphasis on continuous performance improvement and accountability

ii. Re-evaluation of KPI effectiveness to reflect 360° performance

iii. Continuing to promote the expansion of equitable access to all LMICs.

iv. Initiating pilot projects to reduce product lead times in line with end-to-end supply initiatives

v. Building on partnerships to openly address issues and to look actively for common solutions

vi. Rationalising product portfolios

e. **Quality assurance;** promoting equitable access to quality health assured products.

i. More proactively managing quality and other risks

ii. Encouraging broad national registration footprint

iii. Evolving Expert Review Panel to be more strategically focused

iv. Mitigating risks by addressing product quality and safety issues and by encouraging geographic diversity of API and FPP

5. The Procurement Strategy includes for antimalarial medicines several measures related to securing the supply of artemisinin for artemisinin-containing products.

   To be eligible, Bidders must meet the following preconditions:

   a. Environmental Health and Safety (EHS) Issues: Bidders understand that only Panel Artemisinin Manufacturers (Schedule G) shall be used to source artemisinin for artemisinin-containing medicines for the Pooled Procurement Mechanism and Co-payment Mechanism to be supplied under Strategic Partnership Agreements. Bidders also undertake to assess and monitor over time compliance with EHS standards of Panel Artemisinin Manufacturers in their supply chain for artemisinin-containing medicines to be supplied under Strategic Partnership Agreements, and Bidders agrees they will update the Global Fund over time accordingly as specified in the Strategic Partnership Agreement.

   b. Bidders can suggest a new Artemisinin Manufacturer to be included in the Panel list. The request will have to be submitted to the Global Fund with the supporting documents related to EHS compliance performed by the Bidder. The Global Fund reserves the right to approve or not the addition of the new Panel Artemisinin manufacturer. The Bidder will only be able to use the Artemisinin manufacturer after the formal approval from the Global Fund. Once approved, the name of the Artemisinin Manufacturer will be added to the Global Fund list.

   c. Traceability: For artemisinin-containing medicines Bidders understand that they will be

required to ensure the traceability of the artemisinin production site and artemisinin batch number used in each batch of finished pharmaceutical product supplied through a Strategic Partnership Agreement.

d. Bidders are requested on annual basis to describe their business relationships with Panel Artemisinin Manufacturers and/or API suppliers to ensure good business practices across the product supply chain. For each Panel Artemisinin Manufacturer in the Bidder's supply chain (whether direct or indirect through an API supplier for products that contain artemisinin), describe the contract duration (in years or months), the allocation of volume (as a percentage) across Panel Artemisinin Manufacturers and the FOB Incoterm Price (in USD/kg) as well as whether artemisinin is purchased from an API manufacturer.

e. *Use of SSA (for artemisinin-containing products):* During the implementation, each year (i.e.,Year 1, Year 2 and Year 3), Bidders will have to declare the share (as a percentage) of total artemisinin that will be constituted by SSA.

f. *Traceability of production site and batch number of artemisinin (for artemisinin-containing products):* In light of the requirement that FPP Panel Suppliers will be responsible for sourcing artemisinin only from Panel Artemisinin Manufacturers for finished products to be supplied through Global Fund Strategic Partnership Agreements, Bidders will confirm whether they are able to track artemisinin production sites and batch numbers immediately from the implementation date or whether additional time will be required to establish a system to do so. If the latter, additional details will be required.

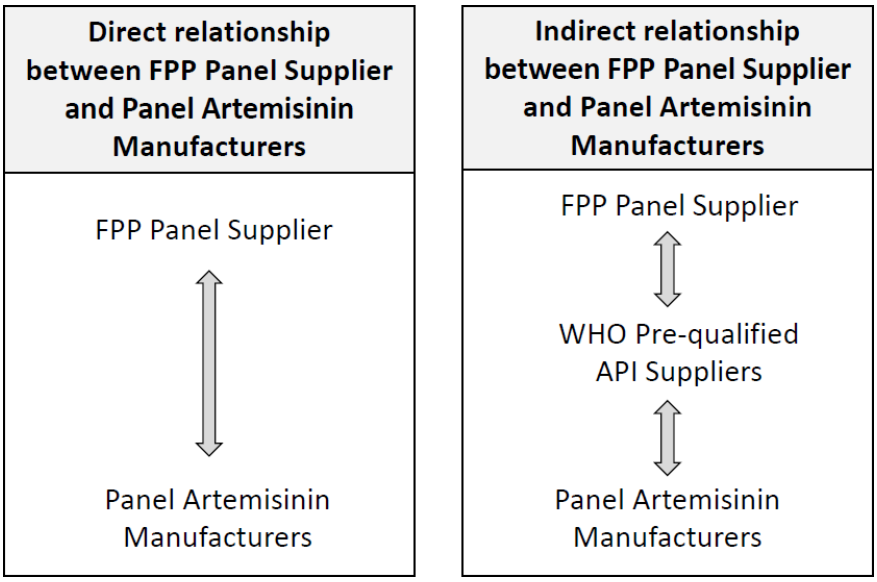
To encourage good business practices across the supply chain, for Bidders with offered products that contain artemisinin, the Global Fund intends to link volume allocations and volume commitments to long term agreements with Panel Artemisinin Manufacturers as summarized in Table 1 below, while reserving the right to adjust if implementation deviates from the Bidder's submission:

Table 1: Volume allocations and commitments for FPP Panel Suppliers for artemisinin-contained products linked to long term agreements to be established with Panel Artemisinin Manufacturers

Long term agreements between Panel Artemisinin Manufacturers and FPP Panel Suppliers (directly or indirectly through their API sources	Volume Allocation	Volume Commitment	FPP Panel Suppliers need to disclose
Unable to prove	Can be a panel supplier but without allocated volumes	None	N/A
12-month contract	12-month allocation	25% of volume allocation	Price, volume, duration, initial volume allocation from contracts between suppliers and Artemisinin manufacturers.
24-month contract	24-month allocation	50% of volume allocation	
36-month contract	36-month allocation	80% of volume allocation	

6. For removal of any doubt, for Bidders offering artemisinin-containing products, all items related to their sourcing of artemisinin described in the RFP apply, whether the artemisinin is sourced directly or indirectly through a WHO Pre-qualified API manufacturer as described in Figure 3.

Figure 3: Linkages between FPP Panel Suppliers and Panel Artemisinin Manufacturers



7. The Global Fund will not be party to the negotiations regarding how FPP Panel Suppliers secure their relationships with Panel Artemisinin Manufacturers. However, all artemisinin to be used in the supply of Finished Pharmaceutical Products to be supplied through Global Fund Framework Agreements can only be sourced from Panel Artemisinin Manufacturers.

8. Under certain circumstances, to secure the supply of artemisinin, the Global Fund may decide to intervene further with Panel Artemisinin Manufacturers. Panel Artemisinin Manufacturers willing and working with three-year contracts will be prioritized over those with two-year contracts, which will be prioritized over those with a one-year contract. Within the same priority band, Panel Artemisinin Manufacturers with the lowest ceiling prices will have higher priority within the band.

9. With the aim of de-risking the artemisinin supply and facilitating the uptake of alternative technologies which includes the use of SSA material, the Global Fund expects the FPP panel suppliers to use SSA material for up to 20% of their artemisinin requirements, if the price of SSA is at or below the average vegetal price and uptake by FPP manufacturers is limited, The Global Fund reserves the right, in its sole discretion, to consider as a risk, any FPP Panel Suppliers not using SSA where conditions are met and will be reflected in the risk assement prior to annual allocation , The Global Fund will ensure any semi-synthetic manufacturer is able to provide adequate technical support for finished pharmaceutical product and active pharmaceutical ingredient manufacturers to fulfil requirements of regulatory variations.

C. PRODUCT SEGMENTATION

1. Products in scope for this RFP include WHO-recommended antimalarial and antiretroviral medicines and other selected medicines used in HIV programs, that are eligible for procurement with Global Fund funding, as noted in the List of Malaria and Antiretroviral Pharmaceutical Products and in the List of Antihepatitis Pharmaceutical Products classified according to the Global Fund Quality Assurance Policy, available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/.

2. To facilitate analysis and RFP management, antimalarial and antiretroviral medicines and other selected medicines for HIV programs have been categorized into the following product sets based on market dynamics and/or relative volume, as summarized in the table below.

Pharmaceuticals **Product Sets:**

Product Group	Characteristics
Group 1: Strategic products	• Growing market • Need to increase the number of suppliers
Group 2: Mainstream products	• Mature market • Need to maintain an average number of suppliers • Promoting competition to keep prices competitive • Steady or increasing demand • High volume products
Group 3: Limited use products	• Declining market • To maintain a limited number of suppliers • Used in special circumstances • Advance HIV disease products
Group 4: Phasing out products	• Declining demand • No need of additional suppliers • Transitioning products
Group 5: Pipeline Products	• New formulation + New molecules • Existing Products (Schedule D) when additional manufacturer is needed

3. Schedule D shows all products withing the scope of this RFP and segmentation.

D. ALLOCATED AND COMMITTED VOLUME (For Strategic Partnership Agreement only)

1. The total forecasted demand for Pharmaceuticals covered by this RFP is as shown in Schedule F.

2. There is no forecasted volume for allocation through the Rapid Supply Mechanism (as defined and discussed below) in this RFP; however, there may be additional volumes available to Bidders able to contribute to a Rapid Supply Mechanism. Bidders' final price submissions procured through the PPM under this RFP will also apply to RSM product.

3. Through this RFP, for certain products, allocated and committed volumes for Pharmaceuticals may be specified in Strategic Partnership Agreements (Schedule C1 of RFP) as described below. As previously stated, for the avoidance of doubt, allocated volumes shall not be legally binding unless expressly and unconditionally stipulated as such in a duly executed Strategic Partnership Agreement.

a. **For PPM**, for certain products, allocated and committed volumes for each FPP Panel Supplier will be specified in the Strategic Partnership Agreement, where, as described in the Strategic Partnership Agreement, the committed volume of Pharmaceuticals is underwritten by the Global Fund.

b. **For CPM**, allocated volumes will be conditional on FPP Panel Suppliers submitting timely Requests for Co-payment in line with the volumes and demand levers for each participating country and shall be subject to review and approval by the Global Fund. The Global Fund reserves the right to adjust these commitments by working with affected FPP Panel Suppliers should the demand levers, subsidy percentages, available funding or eligible First Line Buyers change during the period of the Strategic Partnership Agreement.

c. The Global Fund will also review CPM volume draw down periodically during the term of the Strategic Partnership Agreements, and should an FPP Panel Supplier be unable to supply volumes as initially allocated or as required by the country-specific demand levers and effective grant period, then the Global Fund reserves the right to re-allocate the volume to other FPP Panel Suppliers.

4. Operational management of PPM orders is described as follows:

   a. **PPM:** The Global Fund's selected Procurement Services Agent for Pharmaceutical Products will perform operational management of the procurement of these medicines under the PPM pursuant to the Strategic Partnership Agreements entered into between FPP Panel Suppliers and the Global Fund, including the placement of purchase orders, monitoring of supplier performance, and tracking of purchases which count towards the Global Fund's volume commitment. The current Procurement Services Agent may be replaced by another Procurement Services Agent at any time during the implementation of the Strategic Partnership Agreement.

   b. **CPM:** Operational management of confirmations of co-payment to be issued to FPP Panel Suppliers under the Co-Payment Mechanism will be managed directly by the Global Fund. The CPM principles, requirements and operational management are detailed in the Strategic Partnership Agreement.

5. Pursuant to the Strategic Partnership Agreement, failure to meet performance requirements for quality or delivery, or for artemisinin-containing products, sourcing of artemisinin from suppliers not on the list of Panel Artemisinin Manufacturers will result in the Global Fund taking the remedial actions it deems appropriate. Such remedial actions may include, without limitation, re-allocating the supplier's committed volume across the remaining FPP Panel Suppliers, removal from the supplier Panel, and/or use of other suppliers. Further, if an FPP Panel Supplier cannot meet the required lead times for a specific order as per agreed commitments, this could also result in a corresponding deduction in their allocated and committed volumes.

6. The allocation of product volumes, resulting from this RFP, by the Global Fund to selected FPP Panel Suppliers is conducted at the end of the evaluation process and is described here for information purposes only.

7. The Global Fund will allocate product volumes (including committed volumes in some instances) by distributing the total allocated volume among successful Bidders in proportion to their relative scores and subject to any overall caps established and any identified implementation challenges.

8. For certain products, a portion of the available volumes may be reserved:

    - for subsequent negotiation with newly eligible suppliers and with existing FPP Panel Suppliers that can offer products that become compliant with the Global Fund Quality Assurance Policy after the close of this RFP. If no new entrants emerge, this volume will be released to existing FPP Panel Suppliers on a six-monthly basis according to performance.

9. There is no minimum allocation to any supplier of Pharmaceuticals who is selected as an FPP Panel Supplier, and there is no guarantee that all current suppliers with effective Strategic Partnership Agreements for the supply of Pharmaceutical Products will be selected as FPP Panel Suppliers through this RFP.

10. Upon and subject to successful completion of the RFP process, the Global Fund intends to notify selected FPP Panel Suppliers and the proposed volume allocations and commitments on the date as detailed in Section 3B. Neither this target date nor any communication of proposed volume commitments shall create any legal rights of FPP Panel Suppliers or third parties; only volume commitments expressly and unconditionally stipulated as such in a duly executed Strategic Partnership Agreement shall be legally binding.

11. A final agreement with any proposed FPP Panel Supplier is subject to the signing of the Strategic Partnership Agreement between that Supplier and the Global Fund. If the Global Fund and a proposed FPP Panel Supplier do not come to a final written agreement, including due to protracted or unsuccessful contractual negotiations or material proposed amendments by the Supplier to the Strategic Partnership Agreement provided by the Global Fund in this RFP, the Global Fund will take appropriate action at its discretion, including, without limitation, re-allocating the proposed allocation to another proposed FPP Panel Supplier. The Strategic Partnership Agreement template (Schedule C1 of RFP) reflects Global Fund's standard terms and conditions. Limited non-material changes to the Strategic Partnership Agreement if justified could be considered by the Global Fund. However, Bidders acknowledge and agree that the sections related to compliance with Global Fund policies, Record-Keeping and Audits, the Governing Law and Dispute Resolution, No Waiver of Privileges and Immunities, compliance with the Global Fund's Code of Conduct for Suppliers and the Sanctions Panel Procedures, and the principles of the Most Favoured Nation Section of the Framework Agreement are not subject to change.

12. As described in the Strategic Partnership Agreement template (Schedule C1 of RFP), any volumes to be allocated, including committed volumes, in subsequent calendar years will be subject to the considerations described above and will also be dependent on each FPP Panel Supplier's performance.

E. PRICING

1. During proposal submission, all pricing will be on an open book basis, with cost broken down into a series of elements as defined in the RFP templates.
2. Under the Strategic Partnership Agreement, pricing will be reviewed by the Global Fund as part of the annual supplier performance reviews and/or allocation and commitment process. If, as a result of such review, the Global Fund and the supplier concerned are unable to reach an agreement on the pricing for the next 12-month period, then the Global Fund reserves the right to either re-allocate or re-tender the affected volumes.
3. The Global Fund intends to offer access to product-specific prices to other buyers, as defined in the Strategic Partnership Agreement template (Schedule C1 of RFP), to be finalized as per mutual agreement.

4. The Strategic Partnership Agreement includes a 'most favoured nation' clause for the benefit of the Global Fund (see Schedule C1 of RFP for more information).

F. PRODUCT, PACKAGING & QUALITY ASSURANCE REQUIREMENTS

All the requirements related to Product, Packaging & Quality Assurance are set forth in the Strategic Partnership Agreement and the Purchase Order Agreement.

SECTION 5. LEGAL MATTERS

1. This RFP is in line with and subject to the following documents:

   a. The Global Fund's **Procurement Policy (2008, as amended from time to time)**, which may be found at https://www.theglobalfund.org/media/6389/corporate_procurement_policy_en.pdf;

   b. The **Code of Conduct for Suppliers (2021, as amended from time to time)**, which may be found at: https://www.theglobalfund.org/media/3275/corporate_codeofconductforsuppliers_policy_en.pdf;

   c. The **Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers (2010, as subsequently amended)**, which may be found at: ; https://www.theglobalfund.org/media/6015/corporate_sanctionsprocedures_policy_en.pdf;

   d. The **Global Policy on Conflict of Interest** (2020, as amended from time to time), which may be found at https://www.theglobalfund.org/media/6016/core_ethicsandconflictofinterest_policy_en.pdf?u=637319004468800000

   e. The Strategic Partnership Agreement for FPP Panel Suppliers, and the Purchase Order Agreement, as set forth in Schedule C of the RFP.

2. Personal data (i.e. any information relating to an identified or identifiable natural person) will be treated in compliance with Global Fund's policies and the Privacy Statement for the Global Fund Procurement Process (as amended from time to time).

3. By submitting a proposal for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the Bidder warrants that it has all the necessary power and legal capacity to submit a proposal and eventually enter into a contract. The Bidder also agrees to the terms and conditions of all documents referred to herein and to the following terms:

   a. The Global Fund makes no offer of a contract by posting this RFP or evaluating any proposals submitted in response to it, and there is no legal agreement or relationship, whether in contract (express, implied or collateral) or tort, created by this RFP process between the Global Fund and any bidder, with the sole exception of the provisions of Section 5.

   b. The Global Fund may, at its discretion, change the scheduled time of the key activities of this RFP, or revise this RFP and any of its Schedules, by issuing an amendment to this RFP. All Amendments to this RFP will be posted on the Global Fund website at https://www.theglobalfund.org/en/business-opportunities. It is the Bidder's responsibility to consult the Global Fund's website to ensure that it is aware of amendments to, and additional information for, this RFP.

   c. Global Fund expressly reserves the right to amend, withdraw, or cancel this RFP process and/or its sourcing strategy, change the timeline, and to reject any or all proposals, in whole or in part, at any time and for any reason, without liability or penalty to any party.

   d. This RFP shall not be construed as a contract or a commitment of any kind. This RFP in no way obligates the Global Fund to award a contract.

e. The Global Fund may invite Bidders to make oral presentations in English or to participate in a pre-proposal conference. The date, time and place of such presentation or pre-proposal conference will be formally communicated by the Global Fund to all Bidders or pre-qualified Bidders, as relevant. Any statement made during these meetings shall not in any way amend or modify the RFP, unless it is issued as an amendment to the RFP.

f. The Bidder shall bear all costs associated with the preparation and submission of its proposal, and the Global Fund shall not be responsible or liable for those costs, whether direct or indirect, regardless of the conduct or outcome of the RFP, nor if the RFP is cancelled, altered or postponed for any reason. This includes, but is not limited to, any and all costs incurred for the pre-proposal conferences, clarifications, oral presentations, site visits, visits to the Global Fund, functional demonstrations, and subsequent meetings and negotiations.

g. The Global Fund will not reveal, or discuss with any Bidder how a proposal was assessed, or provide any other information relative to the selection process.

h. Bidders whose proposals are not selected will be notified in writing of this fact, and shall have no claim whatsoever against the Global Fund for any kind of compensation.

i. Any attempt by a Bidder to influence the Global Fund in the examination, evaluation and comparison of proposals, or the recommendation of contract award, or to obtain information thereof through unofficial means, may result in the rejection of its proposal, without prejudice to other rights available to the Global Fund.

j. At any time prior to contracting, the Global Fund reserves the right to: (a) award a contract to the Bidder whose proposal has been determined to be the best evaluated proposal that represents value for money to the Global Fund; (b) reject any or all proposals or price submissions; (c) accept for award a proposal or price submission other than the lowest cost proposal or price submission; (d) accept more than one proposal or price submission; (e) accept alternate proposals or price submissions; (f) accept part of a proposal or price submission; (g) waive informalities and minor irregularities in proposals or price submissions received; or (h) withdraw an award in case of changed circumstances.

k. There are no other arrangements or understandings between any Bidder and the Global Fund with respect to this RFP other than the text contained herein.

l. The investigative, decision-making, and sanctions policies and processes of the Global Fund, including the activities of its Inspector General, the Global Fund's Code of Conduct for Suppliers, and consideration of any findings of fraud or abuse by the Global Fund Sanctions Panel, should the Global Fund in its sole discretion choose to refer the matter to the Sanctions Panel, can and shall apply to (i) this RFP, (ii) the resulting contract, and (iii) any other matter relating to procurement of Pharmaceutical pursuant to this RFP, and these processes may include, without limitation, public disclosure at the Global Fund's full discretion of any findings and/or decisions.

m. The Global Fund has full discretion to investigate any potential fraud or abuse, whether occurring in the past, present or future, associated with the procurement of Pharmaceutical, and the Global Fund at its full discretion may publish the findings of such investigations; through participation in this RFP process, the Bidder acknowledges these processes and shall not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of Pharmaceutical pursuant to this RFP, the dissemination of investigation findings and the responses undertaken by

the Global Fund to findings of fraud or abuse, in all cases whether occurring in the past, present or future.

n. Through its participation in the RFP process, the Bidder acknowledges and confirms that the Global Fund has the right to require that a provision be included in its contracts, requiring suppliers, service providers, contractors and/or consultants to permit the Global Fund or its representative to inspect their accounts, records and other documents relating to the proposal submission and the contract, and to audit them or have them audited by auditors appointed by the Global Fund.

o. The Bidder acknowledges and agrees that pursuant to the Global Fund policies and procurement procedures, the Global Fund may publish certain information consistent with its public status and commitment to transparency. As such, should the Bidder be awarded a contract, the Bidder acknowledges and agrees that the Global Fund may publish certain information relating to procurement contract awards, including without limitation the Bidder's name, as disclosed on its website.

p. Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process, shall be finally settled by arbitration conducted in accordance with the United Nations Commission on International Trade Law (UNCITRAL). The number of arbitrators shall be one; the appointment authority for such arbitrator shall be the International Chamber of Commerce International Court of Arbitration. The place of arbitration shall be Geneva, Switzerland, and the language used at the arbitration shall be English.

q. Nothing contained in this RFP may be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund, whether as of the date of this RFP or thereafter.

Schedule A
Officer's Certificate of Conformance and Acknowledgement

*****

Issued Separately

*****

Schedule B
Confidentiality Agreement (if requested by the bidder)

*****

Issued Separately

*****

REQUEST FOR PROPOSALS (RFP) TGF-D-00014

Schedule C
Draft of Framework Agreement between the Global Fund and FPP Panel Suppliers

*****

Issued Separately in a Later Stage (mid-April 2022)

*****

- C1: Strategic Partnership Agreement
- C2: Purchase Order Agreement

Schedule D
Product segmentation ANTM

Product set 1: Strategic Products

Item Code	Product Description
10376	Artesunate 30mg powder for solution for injection, 1 vial
10100	Artesunate 60mg powder for solution for injection, 1 vial
10337	Artesunate 120mg powder for solution for injection, 1 vial
10331	Amodiaquine + Pyrimethamine/Sulfadoxine 76.5mg + 12.5/250mg 3 dispersible tablet + 1 dispersible tablet, pack of 50 blisters
10332	Amodiaquine + Pyrimethamine/Sulfadoxine 153mg + 25/500mg 3 dispersible tablet + 1 dispersible tablet, pack of 50 blisters
10971	Amodiaquine (as hydrochloride)+Sulfadoxine/Pyrimethamine 75mg+250/12.5mg 3+1 tablet dispersible co-blistered 50 blister
10972	Amodiaquine (as hydrochloride)+Sulfadoxine/Pyrimethamine 150mg+500/25mg 3+1 tablet dispersible co-blistered 50 blister
10396	Dihydroartemisinin/Piperaquine 20/160mg 3 dispersible tablet, 1 blister
11527	Dihydroartemisinin/Piperaquine 20/160mg 3 dispersible tablet, pack of 2 blisters
10973	Dihydroartemisinin/Piperaquine 20/160mg 3 dispersible tablet, pack of 25 blisters
10109	Dihydroartemisinin/Piperaquine 30/240mg 3 dispersible tablet, pack of 2 blisters
10106	Dihydroartemisinin/Piperaquine 30/240mg 3 dispersible tablet, 25 blisters
10397	Dihydroartemisinin/Piperaquine 40/320mg 3 tablet, 1 blister
10398	Dihydroartemisinin/Piperaquine 40/320mg 6 tablet, 1 blister
11529	Dihydroartemisinin/Piperaquine 40/320mg 9 tablet, 1 blister
10400	Dihydroartemisinin/Piperaquine 40/320mg 12 tablet, 1 blister
13111	Dihydroartemisinin/Piperaquine 40/320mg 3 tablet, pack of 25 blisters
13112	Dihydroartemisinin/Piperaquine 40/320mg 6 tablet, pack of 25 blister
10975	Dihydroartemisinin/Piperaquine 40/320mg 9 tablet, pack of 25 blisters
11528	Dihydroartemisinin/Piperaquine 40/320mg 3 dispersible tablet, pack of 2 blisters
10974	Dihydroartemisinin/Piperaquine 40/320mg 3 dispersible tablet, pack of 25 blisters
10108	Dihydroartemisinin/Piperaquine 60/480mg 6 tablet, 1 blister
10103	Dihydroartemisinin/Piperaquine 60/480mg 6 tablet, pack of 25 blisters
10104	Dihydroartemisinin/Piperaquine 80/640mg 6 tablet, 1 blister
10105	Dihydroartemisinin/Piperaquine 80/640mg 6 tablet, pack of 25 blisters
10381	Artesunate/Pyronaridine 20/60mg oral granules sachet, pack of 90 sachet
10380	Artesunate/Pyronaridine 60/180mg tablet 9 tablet 10 blister

Product set 2: Mainstream Products

Item Code	Product Description
10001	Artemether/Lumefantrine 20/120mg 6 tablet, pack of 30 blisters
10002	Artemether/Lumefantrine 20/120mg 12 tablet, pack of 30 blisters
10003	Artemether/Lumefantrine 20/120mg 18 tablet, pack of 30 blisters
10004	Artemether/Lumefantrine 20/120mg 24 tablet, pack of 30 blisters
10005	Artemether/Lumefantrine 20/120mg 6 dispersible tablet, pack of 30 blisters
10006	Artemether/Lumefantrine 20/120mg 12 dispersible tablet, pack of 30 blisters
10377	Artemether/Lumefantrine 40/240mg 6 tablet, pack of 30 blisters
10877	Artemether/Lumefantrine 40/240mg 12 tablet 30 blisters
29192	Artemether/Lumefantrine 40/240mg tablet dispersible, 6 tablets pack of 30 blisters
10378	Artemether/Lumefantrine 60/360mg 6 tablet, pack of 30 blisters
10958	Artemether/Lumefantrine 80/480mg 6 tablet, 1 blister
10379	Artemether/Lumefantrine 80/480mg 6 tablet, pack of 30 blisters
10007	Amodiaquine/Artesunate 67.5/25mg 3 tablet, pack of 25 blisters
10008	Amodiaquine/Artesunate 135/50mg 3 tablet, pack of 25 blisters
10009	Amodiaquine/Artesunate 270/100mg 3 tablet, pack of 25 blisters
10010	Amodiaquine/Artesunate 270/100mg 6 tablet, pack of 25 blisters
10336	Pyrimethamine/Sulfadoxine 25/500mg 3 tablet, pack of 10 blisters
10107	Pyrimethamine/Sulfadoxine 25/500mg 3 tablet, pack of 50 blisters
10959	Pyrimethamine/Sulfadoxine 25/500mg 3 tablet, pack of 10 blisters 5 boxes
10335	Pyrimethamine/Sulfadoxine 25/500mg 3 tablet, pack of 100 blisters
10334	Pyrimethamine/Sulfadoxine 25/500mg tablet, container of 100 tablets
10333	Pyrimethamine/Sulfadoxine 25/500mg tablet, container of 1000 tablets
29150	Pyrimethamine/Sulfadoxine 25/500mg tablet dispersible 10 tablet 10 blisters
29152	Pyrimethamine/Sulfadoxine 25/500mg tablet dispersible, 3 tablets 1 blister
29153	Pyrimethamine/Sulfadoxine 25/500mg tablet dispersible, 3 tablets 10 blisters
29154	Pyrimethamine/Sulfadoxine 25/500mg tablet dispersible, 3 tablets 50 blisters
29344	Pyrimethamine/Sulfadoxine 12.5/250mg 3 dispersible tablets, pack of 100 blisters
29155	Pyrimethamine/Sulfadoxine 12.5/250mg tablet dispersible, 3 tablets 50 blisters
29156	Pyrimethamine/Sulfadoxine 12.5/250mg tablet dispersible, 3 tablets 25 blisters
25463	Pyrimethamine/Sulfadoxine 12.5/250mg tablet dispersible, 10 tablets 11 blisters
25465	Pyrimethamine/Sulfadoxine 12.5/250mg dispersible tablet, 3 tablets, pack of 10 blisters
29157	Pyrimethamine/Sulfadoxine 12.5/250mg tablet dispersible, 3 tablets 1 blister

Product set 3: Limited use Products

Item Code	Product Description
10406	Artesunate 100mg suppository, pack of 2 suppositories
10390	Chloroquine 250mg as phosphate (155mg as base) tablet, container of 100 tablets
10392	Chloroquine 250mg as phosphate (155mg as base) tablet, container of 1000 tablets
10393	Chloroquine 250mg as phosphate (155mg as base) 10 tablet, pack of 10 blisters (100)
10394	Chloroquine 250mg as phosphate (155mg as base) 10 tablet, pack of 100 blisters (1000)
10402	Primaquine 7.5mg (as base) (equivalent to 13.2mg Primaquine Phosphate) tablet, container of 1000 tablets
10403	Primaquine 7.5mg (as base) (equivalent to 13.2mg Primaquine Phosphate) 10 tablet, pack of 10 blisters (100)
10404	Primaquine 7.5mg (as base) (equivalent to 13.2mg Primaquine Phosphate) 10 tablets, pack of 100 blisters (1000)
11543	Quinine 300mg 10 tablets, pack of 10 blisters (100)
11530	Quinine 300mg tablet, container of 100 tablets
11531	Quinine 300mg tablet, container of 1000 tablets

Product set 4: Phasing out Products

Item Code	Product Description
10385	Artesunate/Mefloquine 100/200mg 6 tablet, 1 blister

Product set 4: Pipeline Products

Product Description
Ganaplacide/Lumefantrine
Cipargamin
Ferroquine
Tafenoquine Paediatric
Artesunate injectables
DHA/PPQ
Co-blister AQ/SP

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Schedule D
Product segmentation ARV

Product set 1: Strategic Products

Item Code	Product Description
13330	Dolutegravir 10mg dispersible tablet, container of 90 tablets - no carton

Product set 2: Mainstream Products

Item Code	Product Description
10013	Abacavir/Lamivudine 120/60mg dispersible tablet, container of 30 tablets
13326	Abacavir/Lamivudine 120/60mg dispersible tablet, container of 30 tablets - no carton
10373	Abacavir/Lamivudine 120/60mg dispersible tablet, container of 60 tablets
13327	Abacavir/Lamivudine 120/60mg dispersible tablet, container of 60 tablets - no carton
10014	Abacavir/Lamivudine 600/300mg tablet, container of 30 tablets
13328	Abacavir/Lamivudine 600/300mg tablet, container of 30 tablets - no carton
10022	Atazanavir/Ritonavir 300/100mg tablet, container of 30 tablets
13329	Atazanavir/Ritonavir 300/100mg tablet, container of 30 tablets - no carton
13331	Dolutegravir 50mg tablet, container of 30 tablets - no carton
25625	Dolutegravir/Lamivudine/Tenofovir alafenamide 50/300/25 mg tablet, container of 30 tablets - no carton
10868	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet, container of 180 tablets - no carton
10862	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet, container of 30 tablets - no carton
10867	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet, container of 90 tablets - no carton
10881	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet, container of 30 tablets - no carton
10873	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet, container of 90 tablets - no carton
10041	Emtricitabine/Tenofovir 200/300mg tablet, container of 30 tablets
13332	Emtricitabine/Tenofovir 200/300mg tablet, container of 30 tablets - no carton
10050	Lamivudine/Tenofovir 300/300mg tablet, container of 30 tablets
13333	Lamivudine/Tenofovir 300/300mg table, container of 30 tablets - no carton
10051	Lamivudine/Zidovudine 150/300mg tablet, container of 60 tablets
13334	Lamivudine/Zidovudine 150/300mg tablet, container of 60 tablets - no carton
10052	Lamivudine/Zidovudine 30/60mg dispersible tablet, container of 60 tablets
29111	Lamivudine/Zidovudine 30/60mg dispersible tablet, container of 60 tablets - no carton
10063	Lopinavir/Ritonavir 200/50mg tablet, container of 120 tablets
13336	Lopinavir/Ritonavir 200/50mg tablet, container of 120 tablets - no carton
10066	Nevirapine 10mg/mL oral suspension, 100mL bottle
10082	Zidovudine 50mg/5mL oral solution, 240mL bottle

Product set 3: Limited use Products

Item Code	Product Description
	ARV
10969	Abacavir/Dolutegravir/Lamivudine 600/50/300mg tablet, container of 30 tablets - no carton
10320	Darunavir 150mg tablet, container of 240 tablets
10317	Darunavir 400mg tablet, container of 60 tablets
10027	Darunavir 600mg tablet, container of 60 tablets
10319	Darunavir 75mg tablet, container of 480 tablets
10870	Darunavir/Ritonavir 400/50mg tablet, container of 60 tablets
11555	Dolutegravir/Emtricitabine/Tenofovir alafenamide 50/200/25mg tablet, container of 30 tablets - no carton
10375	Lamivudine 10mg/mL oral solution, 240mL bottle
10058	Lopinavir/Ritonavir 40/10mg capsule (pellets), container of 120 capsules
10322	Raltegravir 100mg chewable tablet, pack of 60 tablets
13267	Raltegravir 100mg oral granules sachet, pack of 60 sachets
10323	Raltegravir 25mg chewable tablet, pack of 60 tablets
25415	Raltegravir 400mg tablet, container of 60 tablets
10096	Ritonavir 100mg tablet, pack of 30 tablets
10324	Ritonavir 25mg tablet, pack of 30 tablets
10077	Tenofovir 300mg tablet, pack of 30 tablets
10089	Etravirine 100mg tablet, container of 120 tablets
10318	Etravirine 25mg tablet, container of 120 tablets
	Other selected medicines used in HIV programs
10910	Daclatasvir 30mg tablet, container/pack of 28 tablets
10911	Daclatasvir 60mg tablet, container/pack of 28 tablets
10904	Entecavir 0.5mg tablet, container/pack of 30 tablets
10908	Entecavir 0.5mg single-scored tablet, container/pack of 90 tablets
10905	Entecavir 1mg tablet, container/pack of 30 tablets
10909	Entecavir 1mg single-scored tablet, container/pack of 90 tablets
10918	Flucytosine 10mg/mL solution for parenteral injection, 250mL IV bottle
10917	Flucytosine 500mg tablet, container/pack of 100 tablets
15270	Isoniazid 100mg 10 dispersible tablets, pack of 10 blisters (100)
10913	Isoniazid 100mg 10 tablets, pack of 10 blisters (100)
10636	Isoniazid 300mg 28 tablets, pack of 24 blisters (672)
10715	Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300/25/800/160mg tablet, container of 30 tablets
10906	Doxorubicin 2mg/ml pegylated liposomal powder for solution for parenteral injection 20mg vial, 1 vial
10907	Doxorubicin 2mg/ml pegylated liposomal powder for solution for parenteral injection 50mg vial, 1 vial
11525	Rifapentine 150mg tablet 8 tablets, pack of 3 blisters (24)
11550	Isoniazid/Rifapentine 300/300mg 12 tablet, pack of 3 blisters (36)
10902	Sofosbuvir 400mg tablet, container/pack of 28 tablets
10912	Sofosbuvir/Ledipasvir 400mg/90mg tablet, container/pack of 28 tablets
10964	Sofosbuvir + Daclatasvir 400mg + 60mg tablets, co-blistered pack of 28 blisters
11526	Sofosbuvir/Velpatasvir 400mg/100mg tablet, container/pack of 28 tablets

Product set 4: Phasing out Products

Item Code	Product Description
10880	Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet, container of 30 tablets - no carton
10860	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet, container of 30 tablets - no carton
10882	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet, container of 90 tablets - no carton
10062	Lopinavir/Ritonavir 100/25mg tablet, container of 60 tablets
13335	Lopinavir/Ritonavir 100/25mg tablet, container of 60 tablets - no carton
10950	Lopinavir/Ritonavir 40/10mg oral granules sachet, pack of 120 sachets

Product set 5: Pipeline Products

Abacavir/Dolutegravir/Lamivudine 60/30/5 mg
Cabotegravir
Dapivirine vaginal ring
Darunavir/Ritonavir 120mg /20 mg
Dual Pill (combination contraceptive and HIV PrEP)
Islatravir
Lenacapavir
TAF-XTC or TAF-XTC-DTG (TAF-FTC 25mg/200mg)

Schedule E
Response Templates

These are presented as two separate Excel Files:

- E1: Technical
- E2: Commercial

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Issued Separately

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Schedule F
Demand Forecast for ARVs

Below is an indicative annual demand forecast for the 12 months of calendar year 2023 based on information available. Overall volumes are not anticipated to be lower in subsequent calendar years although the proportions of the various products will vary as country regimens change especially for first line tenofovir and dolutegravir containing products.

Note that volumes are not provided for some lower volume products with limited or no demand visibility.

Number of packs 2023		
Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet	** without secondary carton* ** may be procured in various sizes, but expressed as packs of 30 for forecasting purposes*	62,840,000
Dolutegravir 50mg tablet 30		2,000,000
Abacavir/Lamivudine 120/60mg tablet dispersible (expressed as a pack of 30)		Abacavir/Lamivudine 120/60mg tablet dispersible (expressed as a pack of 30)
Dolutegravir/Emtricitabine/Tenofovir alafenamide 50/200/25mg tablet 30 – no carton		1,500,000
Abacavir/Lamivudine 600/300mg tablet 30		1,200,000
Dolutegravir 10mg tablet 90		1,000,000
Emtricitabine/Tenofovir 200/300mg tablet 30		600,000
Nevirapine 10mg/ml oral suspension 100ml		600,000
Lamivudine/Tenofovir 300/300mg tablet 30		500,000
Lamivudine/Zidovudine 150/300mg tablet 60		500,000
Lamivudine/Zidovudine 30/60mg tablet dispersible 60		500,000
Atazanavir/Ritonavir 300/100mg tablet 30		400,000
Lopinavir/Ritonavir 200/50mg tablet 120		300,000
Zidovudine 50mg/5ml Oral solution 240ml		200,000
Ritonavir 100mg tablet (expressed as a pack of 30)		30,000
Darunavir 600mg tablet 60		30,000
Others		800,000
Total packs (all products)		75,000,000

Schedule F
Demand Forecast for ANTM

Below is an indicative annual demand forecast for the 12 months of calendar year 2023 based on information available. Overall volumes are not anticipated to be lower in subsequent calendar years

Number of packs 2023	
Artemether + Lumefantrine	3,333,335
Artesunate + Amodiaquine tablets	512,000
Artesunate injectables	17,000,000
SMC campaign: Amodiaquine + Sulfadoxine-Pyrimethamine tablets	1,900,000
Sulfadoxine + Pyrimethamine 500/25mg (3 tablet 100 blisters)*	166,665
Primaquine 7.5mg 10 tablet 10 blister	100,000
Artesunate suppository 100mg	170,000
Chloroquine 250mg 10 tablet 10 blister	20,000
Quinine sulphate 300mg 10 tablet 10 blister	15,000
Piperaquine tetraphosphate + Dihydroartemisinin	Not available yet
Artesunate + Pyronaridine	Not available yet
Total packs (all products)	23,217,000

*packs converted into one packaging for forecast purpose. Different packagings will be procured.

Schedule G
List of the Panel Artemisinin Manufacturers

1. Bionexx
2. Chongqing Holley Wuling Mountain Pharma
3. Chongqing Kerui Nanhai Pharmaceutical
4. Guangxi Xian Caotang Pharmaceutical
5. Hunan Vigor Bio Tech Co Ltd
6. Huvepharma
7. Jiangsu Swellxin Bio-Pharm.
8. Sichuan Lambert Bio-Tech, they quited the arti business in2019
9. Sichuan Tongrentai Pharmaceutical
10. Wuling Sunshine Biotech
11. Xiangxi Aoruike Pharmaceutical Chemical
12. Yongzhou Xingcheng Bio-Tech (Hunan Xingchen Biotechnology)

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Schedule H
Integrity Due Diligence (IDD) questionnaire

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