REQUEST FOR PROPOSALS (RFP) TGF-18-010

ANTIRETROVIRAL AND OTHER SELECTED MEDICINES USED IN HIV PROGRAMS

Issue Date: 1 February 2018

RFP Closing Date: 16 March 2018

RFP Closing Time: 17.00 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 Antiretroviral Medicines during 2018 to 2021 to, or on behalf 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:

SCHEDULE B	Form of Confidentiality Agreement *(if requested by the Bidder*)
SCHEDULE C	Draft of Framework Agreement between the Global Fund 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) • **E3:** For Information and Implementation (Excel File)
SCHEDULE F	Demand forecast for ARVs

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

Should you require any clarification, kindly communicate only with the contact person identified in Section 3.E.3 regarding communication during the RFP as the focal point for queries on this RFP.

SECTION 2. DEFINITIONS

1. **Allocated volume (or volume allocation):** Volume of antiretroviral and other selected medicines used in HIV programs 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.

2. **Antiretroviral Medicines (ARVs)**: World Health Organization (WHO)-recommended medicines to supress the HIV virus and stop the progression of HIV disease.

3. **API:** Active Pharmaceutical Ingredient

4. **Base price:** Price of the product to be offered to the Global Fund through a Framework Agreement.

5. **Bidder**: Supplier who submits a proposal by the deadline for this RFP.

6. **Committed volume (or volume commitment):** Volume of antiretroviral and other selected medicines used in HIV programs that the Global Fund undertakes to underwrite financially through a fully executed Framework Agreement "Strategic Partnership Agreement" (Schedule C of RFP), and for which the FPP Panel Supplier agrees to provide to Committed Volume Buyers, during the period specified and at the prices specified in the Framework Agreement.

7. **Finished Pharmaceutical Product (FPP) manufacturers:** Manufacturers of a medicine presented in its finished dosage form.

8. **FPP Panel Supplier**: An FPP manufacturer who has been awarded a Framework Agreement by the Global Fund for the supply of antiretroviral medicines. The outcome of this RFP will establish the FPP Panel Suppliers for antiretroviral medicines.

9. **Global Fund:** The Global Fund to Fight AIDS, Tuberculosis and Malaria. More information is available here: http://www.theglobalfund.org/en/

10. **H2:** Second half of calendar year (i.e., July through December).

11. **HIV:** Human immunodeficiency virus

12. **KSM:** Key Starting Material

13. **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.

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

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

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

17. **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 under this RFP.

18. **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. More information is available at: https://www.theglobalfund.org/en/sourcing-management/health-products/.

19. **Committed Volume Buyer:** Any party which makes a purchase of antiretroviral and other selected medicines used in HIV programs pursuant to the terms of a fully executed Strategic Partnership Framework Agreement (Schedule C of RFP) and as a draw-down of the Committed Volume under the Framework 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 Framework Agreement will specify that the Global Fund may designate additional Committed Volume Buyer(s) during the term of the Framework Agreement, by written notice to the FPP Panel Supplier.

20. **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.

21. **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, Antiretroviral Medicines through the Pooled Procurement Mechanism. The current PSA for ARVs and other selected medicines used in HIV programs is the Partnership for Supply Chain Management. The PSA is subject to change at any time.

22. **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.

23. **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.

24. **Standardized labelling:** FPP labelling without country-specific customization.

25. **Stringent Drug Regulatory Authority (SRA):** A regulatory authority which is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, 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 may be updated from time to time).

26. **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. INSTRUCTION TO BIDDERS

A. CONDITIONS FOR PARTICIPATION

1. This RFP is in line with the Global Fund's **Procurement Regulations (2017, as amended from time to time)**, which may be found at http://www.theglobalfund.org/en/business/. The following documents are therefore integral parts of this RFP:

    a. The **Global Fund Solicitation Rules (2015, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/business/, provided that in case there is any conflict between the special provisions of this RFP and the Global Fund Solicitation Rules, the special conditions of this RFP shall govern;

    b. The **Policy on Ethics and Conflict of Interest for Global Fund Institutions (2002, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance-policies/;

    c. The **Code of Conduct for Suppliers (2009, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance-policies/;

    d. The **Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers (2010, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance-policies/;

    e. The Framework Agreement for FPP Panel Suppliers, as Schedule C of RFP; and

    f. Applicable Procurement Principles of the Global Fund's Procurement Policy, which may be found at: http://www.theglobalfund.org/en/business/.

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 (2009, as amended from time to time) and shall be subject to the Global Fund's Sanctions Procedures Relating to the Code of Conduct for Suppliers (2010, as amended from time to time).

5. Related Firms are not allowed to submit separate bids and are required to determine among themselves which firm is the best suited to submit a bid or submit a consolidated single bid 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 bid 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. 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 bid.
8. All proposals must remain valid for a period of 120 days from the RFP submission deadline.
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	1 February 2018
2. Schedule C issued: Draft of Framework Agreements	9 February 2018
3. Deadline for prospective bidders to submit clarification questions to the RFP	15 February 2018: 17.00 hrs
4. Latest date for the Global Fund to issue responses to clarification questions to all prospective bidders	20 February 2018
5. Deadline for electronic submission of proposal (close of RFP)	16 March 2018: 17.00 hrs
6. Notification of Stage 2 (if needed)	29 March 2018
7. Tentative dates for Stage 2 (if needed)	23-27 April 2018
8. Notification of Awards to Bidders	22 June 2018

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), as applicable, and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2017, as amended from time to time).

   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 evaluation of proposals and recommendation of 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.

   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. Each bidder will review and complete various Schedules and response templates as described below depending upon the type of contract requested.

Schedule		Agreement type	
		Strategic Partnership Agreement	**Purchase Order Agreement[1]**
A	Officer Certificate of Conformance and Acknowledgement	Required submission	Required submission
B	Form of Confidentiality (if required)	Required submission	Required submission
E	Response templates		
	E1: Technical Proposal	Required submission	Required submission: 1a; 1b; 2b
	E2: Commercial Proposal	Required submission	Required submission: Base price 2018
	E3: For Information and Implementation Proposal	Required submission	Required submission: 1, 3, 5

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

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 Framework Agreement (Schedule C). Only reservations or requests for amendments to the Framework 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 2010 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://access.theglobalfund.org/.

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

3. Once in possession of a Supplier ID, all communication must be channeled through the TGF Sourcing Application. Only in exceptional circumstances, such as technical difficulties in accessing the platform, can communication be 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-18-010) and be addressed to the single point of contact Elizabeth.Simpson@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.

2. 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.

3. Proposal Schedules are to be submitted in both of the following formats to ensure no errors occur in the evaluation process:
   a. Schedules E1, E2, and E3 in Excel format.
   b. A signed copy of Schedules E1, E2, and E3 and all other Schedules, in PDF format.

F. EVALUATION OF THE PROPOSAL

1. Upon receipt, 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. In keeping with the range of strategic objectives, the tender 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 Antiretroviral Medicines Strategy, as described in Section 4.

4. Bidders expressing a preference for a Strategic Partnership Agreement will be evaluated as described in this section. Bidders expressing a preference for a Purchase Order Agreement are required to provide requested information for contracting purposes, which may be evaluated.

5. The Global Fund shall evaluate the proposals as described here. 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.

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
1a.	Product coverage	Evaluated information
1b.	Country registration approval coverage	Evaluated information
2a.	On time in full delivery	Evaluated information
2b.	Responsiveness (lead time)	Evaluated information
3a.	Quality Assurance Policy Regulatory Status – WHO Prequalification	Evaluated information
3b.	Quality Assurance Policy Regulatory Status – Stringent Regulatory Authority	Evaluated information
3c.	Supply security and visibility: dolutegravir-containing products	Evaluated information
4.	Projects to deliver on strategic objectives	Evaluated information
5.	Production footprint in sub-Saharan Africa: proximity to high volume demand	Evaluated information

Schedule E2: Commercial Template

Elements		Information Type
1.	Base Price and Total Landed Cost (2018)	Evaluated information
2.	Advanced Purchase Order discount	Evaluated information
3.	Price roadmaps for Global Fund designated strategic ARVs	Evaluated information
4.	Price roadmaps for Global Fund designated strategic non-ARV medicines	Required information*
5.	Cost breakdown	Evaluated information

Schedule E3: For Information and Implementation

Elements		Information Type
1.	Company information	Required information*
2.	Standardized labelling price discount	Required information*
3.	GS1 bar coding standard	Required information*
4.	List of countries where the Bidder is willing to supply as a Committed Volume Buyer	Required information*
5.	Pipeline products being developed/approved	Required information*
6.	Participation on WHO Collaborative Procedure for Accelerated Registration and sub-regional Registration initiatives	Required information*

*Required information may be validated

8. Schedules E1 and E2 collect largely evaluated information. However, some product sets will not be evaluated for all of the elements. The table below provides an overview of which product sets will be evaluated for each element, with additional detail regarding product segmentation provided in Section 4C and Schedule D.

		Schedule E1: Technical response								Schedule E2: Commercial response		
		1a. Product coverage	1b. Country registration approval coverage	2a. OTIF	2b. Responsiveness**	3a and b. Quality Assurance Policy Regulatory Status	3c. Supply security and visibility: dolutegravir-containing products	4. Projects to deliver strategic objectives	5. Production footprint in sub-Saharan Africa	1. Base price	2. Advance Purchase Order Discount	3. Price roadmaps
1. WHO preferred or alternative regimen products		evaluated	evaluated	evaluated	N/A	evaluated	evaluated	evaluated	evaluated	evaluated	evaluated	evaluated***
2. WHO limited use/ specialist	**a) low/medium volume**	evaluated	evaluated	evaluated*	N/A	evaluated	N/A	evaluated	evaluated	evaluated	N/A	N/A
	b) very low volume	evaluated	evaluated	evaluated*	N/A	required information	N/A	evaluated	evaluated	required information	N/A	N/A
	c) not procured in 2016-2017	evaluated	evaluated	evaluated*	N/A	required information	N/A	evaluated	evaluated	required information	N/A	N/A
3. Related products used in HIV programs		evaluated	evaluated	N/A	N/A	required information	N/A	evaluated	evaluated	required information	N/A	required information ****

* For supplier performance reviews during implementation: OTIF will be assessed for Product Set 1 and monitored for Product Sets 2 & 3 [See Section 7 above for more detail.]

** assessed during supplier performance review during implementation. Responsiveness will be assessed for Product Set 1 and monitored for Product Sets 2 & 3 [See Section 7 above for more detail.]

*** for designated strategic ARVs [See Section 7 above and Schedule D for more detail.]

**** for designated strategic non-ARV medicines [See Section 7 above and Schedule D for more detail.]

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

10. Schedule E1: Technical Template

1a. Product coverage: Clarification of the products that are eligible for submission and evaluation:

- "Global Fund Strategic ARVs"[2]: compliant with the Global Fund's Quality Assurance Policy, or for the purpose of evaluation, submitted and accepted for review by the WHO Prequalification Programme, a Stringent Drug Regulatory Authority or the Global Fund's Expert Review Panel[3].
- For other ARVs: compliant with the Global Fund's Quality Assurance Policy.
- For the other (non-ARV) selected medicines used in HIV programmes (Product Set 3) included in this RFP: submitted and accepted for review by the WHO Prequalification Programme or a Stringent Drug Regulatory Authority.

Products not meeting the above requirements will not be evaluated and rather should be described in Schedule E3.5: Pipeline products being developed/approved.

1b. 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 country, including the authorization number, approval date, expiry date, long life validity, annual retention and the retention paid date.

2a. On time in full delivery (OTIF) (based on historical internal data, for all products supplied through Global Fund Framework Agreements in calendar years 2015-2017 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.

2b. Responsiveness (lead time, per product): Responsiveness aims at achieving shorter but realistic lead times for products to be delivered. Lead time measures the time in which a supplier is able to deliver products from Purchase Order Confirmation to the Manufacturer Promised Date. Bidders are required to indicate the standard product-specific lead times between the Purchase Order Confirmation Date and Manufacturer Promised Date, in number of weeks for the indicative purchase order size per product indicated in Schedule E1. The lead time information will not be evaluated in the tender process; however, this information will be used during implementation as part of performance reviews and the allocation process for subsequent periods. This will include measurement of actual product-specific lead time performance compared to the product-specific lead times included in a Bidder's proposal.

3. a. b. c. Quality Assurance Policy Regulatory Status; Supply Security and Visibility: Clarification of approved Finished Pharmaceutical Products and internal and external API sources in the current approved FPP dossier. For each product offered, the following is to be specified: Product Description (formulation), Unit of Measure/Package Unit, Strength Dose, Dosage Form, regulatory approval (including reference number and approved shelf life), country of manufacture, transportation and storage restrictions (if any). Please see Sheet E1.3a

[2] Identified in Schedule D

[3] For the avoidance of doubt, the submission of products in anticipation of compliance with the Global Fund's Quality Assurance Policy is to enable a conditional allocation of key new products only; all products supplied pursuant to this RFP must comply with Global Fund's Quality Assurance Policy, and no commitments or orders will be made in anticipation of approval.

WHO PQ and Sheet E1.3b SRA, for completion, as appropriate. In addition, for suppliers of Dolutegravir/Lamivudine/Tenofovir, information is required regarding current and anticipated stock levels, including API/KSM sources; see Sheet E1.3c for the required information.

4. *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 ARVs 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 objectives of the ARV Procurement Strategy 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 detail should be provided separately to fully articulate the proposal. Priority areas of interest to the Global Fund include, but are not limited to:
    i. Improving responsiveness through the Rapid Supply Mechanism for both emergency requirements and potentially also fulfilling smaller orders (provide detailed proposal detailing products and quantities and approach)
    ii. Achieving manufacturing, packaging and labelling efficiencies
    iii. Achieving shorter lead-times through innovative manufacturing, storage or other supply chain solutions
    iv. Maintaining access to ARV in the declining phase of the product lifecycle as regimens change
    v. Expanding access to the (non-ARV) selected medicines used in HIV programmes included in this RFP

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

5. *Production footprint in sub-Saharan Africa: proximity to high volume demand.* Bidders are required to indicate whether it fully or partially performs any stages of manufacturing at manufacturing sites in sub-Saharan Africa compliant with the Global Fund's Quality Assurance policy. If the Bidder partially or fully performs any manufacturing steps at manufacturing sites in sub-Saharan Africa, the Bidder is required to indicate 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 Framework Agreements will come from a manufacturing site in sub-Saharan Africa where products have undergone all stages of production (full production process), 10% of the total quantity of finished pharmaceutical product, Z, will come from a manufacturing site(s) in sub-Saharan Africa where bulk products are finally packaged and labelled (partial formulation process) and 50% of the total quantity of finished pharmaceutical products will come from manufacturing sites outside of sub-Saharan 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 Framework Agreement (Schedule C of RFP). Proximity to demand considers the time taken for delivery from the manufacturing site to the customer, to be calculated by the Global Fund based on historical transactional and/or market data.

11. Schedule E2: Commercial Template

1. *Base Price and Total Landed Cost (price for 2nd half of calendar year 2018):* 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 historical freight cost data.
2. *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.

3. Price roadmaps for Global Fund designated strategic ARVs*:* Bidders will submit prices offered per product in USD (EXW price) to the nearest cent for calendar year 2019. Should there be any conditionalities related to the pricing, this should be articulated in the comments section.
4. *Price roadmaps for Global Fund designated strategic non-ARV medicines:* Bidders will submit prices offered per product in in USD (EXW price) to the nearest cent for calendar year 2019. Should there be any conditionalities related to the pricing, this should be articulated in the comments section. Products are detailed in Schedule D.
5. *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. Products are detailed in Schedule D.

12. Schedule E3: For Information and Implementation

1. *Company information:* Information relating to the legal name, type, form of organization, country of registration, address, whether part of a related group (and if so, the controlling entity), number of employees worldwide and primary business contact.
2. *Standardized labelling price discount:* Should an agreement be reached for non-customized labeling for use across multiple countries, describe whether a standardized labelling price discount would be offered (as a percentage*).*
3. *GS1 bar coding standards:* Bidders are requested to respond to the questions related to GS1 bar coding standards.
4. *List of countries where the Bidder is willing to supply as a Committed Volume Buyer:* Bidders are requested to identify those countries to which they would be prepared in principle to extend the Framework Contract terms to other public sector buyers and funders such as (i) Governments of host countries (ii) United Nations-related organizations, non-governmental organizations and not-for-profit organizations; and (iii) development and/or public health financing mechanisms.
5. *Pipeline products being developed/approved:* describing progress of products in the product development or regulatory approval pipeline.
6. *Participation on WHO Collaborative Procedure for Accelerated Registration and sub-regional Registration initiatives:* describing the number of products submitted and resulting in a national or regional approval through these schemes.

G. NOTIFICATION AND CONTRACTING

1. The final decision on allocated and committed volumes will be made by the Global Fund and communicated to all selected Bidders. 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 Framework Agreement with such Bidder.

2. Upon and subject to successful completion of the RFP process, the Global Fund intends to notify all bidders of the outcome of the evaluation by a the date detailed in Section 3B.

3. 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.

4. A final qualification with any proposed FPP Panel Supplier is subject to the signature of the Framework Agreement. If a proposed FPP Panel Supplier does not sign a Framework 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 2017-2022 Strategy, ***Investing to End Epidemics***, available at https://www.theglobalfund.org/en/strategy/, are to: maximize impact against HIV, tuberculosis and malaria; build resilient and sustainable systems for health; promote and protect human rights and gender equality; and mobilize increased resources. The strategic objectives and sub-objectives of the Global Fund 2017-2022 Strategy provide a critical path outlining how the Global Fund works with partners to ensure that the response globally and at country level is inclusive, impactful and sustainable.

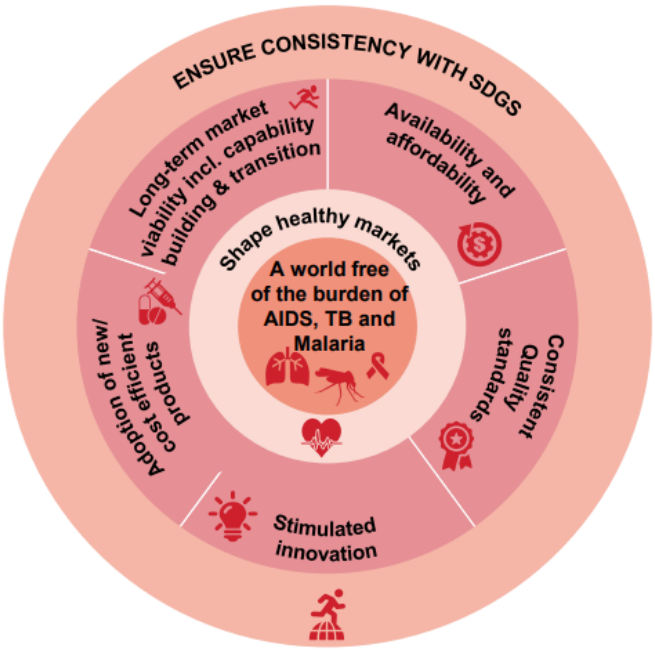
2. In support of the 4th Strategic Objective of the Global Fund 2017-2022 Strategy, to mobilize increased resources, two key operational objectives link directly with the Global Fund's Market Shaping Strategy:

    a. Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies; and

    b. Support efforts to stimulate innovation and facilitate the rapid introduction and scale-up of cost-effective health technologies and implementation models.

3. The Global Fund revised its Market Shaping Strategy, available at https://www.theglobalfund.org/en/sourcing-management/market-shaping-strategy/. The aim of the Market Shaping Strategy is to leverage the Global Fund's position to facilitate healthier global markets for health products, today and in the future. The Market Shaping Strategy includes key objectives to advance this, linked to the Global Fund's vision.

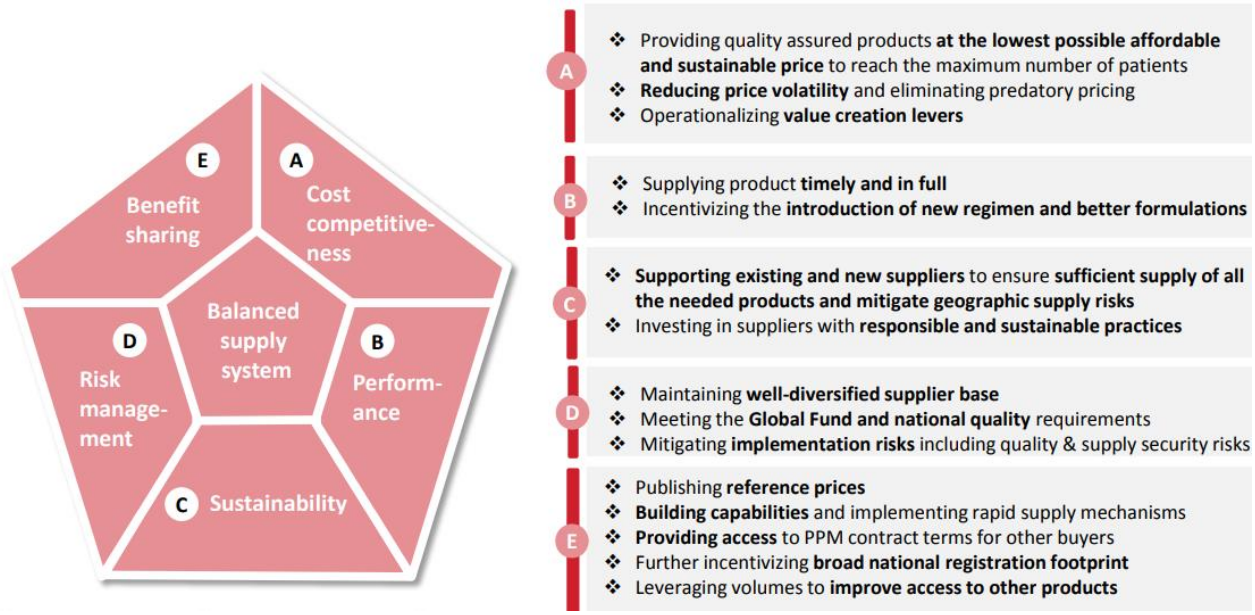
Figure 1. Global Fund Vision and Market Shaping Strategy Objectives



4. The Global Fund's Sourcing Department implements the Market Shaping Strategy 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, including that for Antiretroviral Medicines, 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 Antiretroviral and Other Selected Medicines Used in HIV Programs, described on the Global Fund website, available at https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/, and of which this RFP is a core element, supports the achievement of the Global Fund's market shaping strategic objectives and builds on the experience and lessons learned from the previous Procurement Strategy for Antiretroviral Medicines. The Procurement Strategy was developed based on a combination of analysis of recent market dynamics data and discussions with manufacturers, grant recipients, donors, key partners and other technical agencies. It also includes a renewed emphasis on the following strategic areas: leveraging impact, total cost approach, innovation and product introduction, responsible procurement, principles of information sharing and consistent quality standards, described in further detail via the web link noted above. **For the avoidance of doubt where any presentation documentation of the RFP or the Global Fund's Antiretroviral Medicines Strategy and this RFP differ, this RFP shall prevail.**

B. OBJECTIVES

1. The purpose of this RFP is to select a panel of FPP manufacturers ("FPP Panel Suppliers") who will enter into Framework Agreements with the Global Fund to implement its Procurement Strategy and to supply WHO-recommended Antiretroviral and other selected medicines used in HIV programs procured with Global Fund financing through the Pooled Procurement Mechanism ("**PPM"**).
2. These Framework Agreements will be for a three and half years term from Q3-2018 to end-2021, and may comprise allocated and committed volumes, depending on the products to be supplied, determined at the time of Framework Agreement signature for 2018, 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 Framework Agreement.
3. The aim of the Antiretroviral Medicines Procurement Strategy 2018-2020 is to increase access to all needed WHO-recommended antiretroviral and other selected medicines and formulations used in HIV programs at the optimum price whilst simultaneously maintaining a competitive market (details are available at: https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/: Procurement Strategy 2018-2020: ARVs and Other Strategic Medicines for HIV Programs Presentation (November 2017)).
4. Detailed objectives of the Antiretroviral Medicines Procurement Strategy 2018-2020 to support this aim fall into the following categories and are described in further detail below: sustainable supply; competitive pricing and affordability; availability and reliable delivery; and quality and regulatory.

    a. **Sustainable supply:** *Maintain a sustainable and predictable supply of all needed antiretroviral and other selected medicines used in HIV programs*

        i. Continued supply of all needed ARVs
        ii. De-risk API/KSM supply
        iii. Recognize the value of innovation and accelerate the introduction and uptake of newer (improved) products and formulations
        iv. Promote responsible procurement, including good business practices, through the supply chain
        v. Improve demand management, a key driver of overall supply performance
        vi. Encourage bids and make conditional allocations for strategic products for WHO Pre-Qualified/Stringent Regulatory Authority approvals expected in calendar year 2018.
        vii. Maintain sufficient supplier presence in the market and encourage new entrants who can demonstrate sufficient added value to the Global Fund with volumes being available to include new entrants where needed, especially for products in the early lifecycle stages

    b. **Competitive pricing and affordability (total cost approach)**

        i. Avoid price volatility that could impact achieving Global Fund targets and encourage sustainable (lower) pricing
        ii. Encourage price roadmaps for strategic products
        iii. Improve efficiencies by reducing stock-keeping units (SKUs), cartonless packaging and customization

iv. Allocate longer shelf life products, especially for later lifecycle products with falling sporadic demand

v. Encourage the registration of reduced volume packaging by preferentially allocating these once a product is registered in a country

vi. Require GS1 barcoding standards (aligned with USAID and South Africa)

vii. Engage more proactively regarding the most favoured nation clause

c. Availability and reliable delivery

i. Improve and sustain supplier delivery performance, moving the OTIF target to over 90%

ii. Encourage more responsive supply by:

1. valuing shorter lead times through innovative supply chain solutions;
2. encouraging vender-managed inventory (VMI) and stock visibility for low volume orders and to respond to stock out risks; and
3. further strengthening the Rapid Supply Mechanism through a vendor managed inventory (VMI)

iii. Bundle low and high volume products to support the availability of all needed products

iv. Coordinate procurement with other buyers for low volume/ niche products

v. Support mainstreaming of UNITAID investments in new product introductions

d. Quality and regulatory

i. More proactively manage quality and other risks

ii. Encourage broad national registration footprint

iii. Evolve ERP to be more strategically focused

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

5. The Procurement Strategy includes several new additional measures or periodic reporting requirements related to meeting its objectives:

- Proactive management of the pricing and the implementation of the Most-Favoured Nation Clause of the Framework Agreements (See Schedule C of RFP)
- Reporting of future planned capacity and any constraints for selected products to support the smooth transition to new products
- Reporting on upstream sources and supply visibility of APIs and KSMs

C. PRODUCT SEGMENTATION

1. Products in scope for this RFP include WHO-recommended antiretroviral medicines that are eligible for procurement with Global Fund funding, as noted in the List of 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/. At the time of publication of this RFP, Version 142 of 18 December 2017 was in effect; **please consult the website to confirm the latest version in effect just prior to the close of the RFP**.

2. To facilitate analysis and RFP management, antiretroviral and other selected medicines for HIV programs have been categorized into the following 3 product sets based on their therapeutic use and/or relative volume, as summarized below in Figure 3.

Figure 3. Antiretroviral and other selected medicines used in HIV programs: Product Sets

Product set		Spend	Focus
1. WHO preferred and alternative regimen products		98%	Full scope and leverage of strategy objectives
2. WHO limited use/ specialist products	a) low/medium volume b) very low volume c) not procured in 2016-2017	2%	Availability across multiple procurement channels
3. Other (non-ARV) selected medicines used in HIV programmes		low	Access and affordable pricing to Global Fund & other buyers

3. Schedule D provides more detail on the product scope and segmentation.

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

1. The total forecasted demand for antiretroviral and other selected medicines for HIV programs covered by this tender 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 tender; 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 antiretroviral and other selected medicines used in HIV programs may be specified in Framework Agreements (Schedule C 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 Framework Agreement. For PPM, for certain products, allocated and committed volumes for each FPP Panel Supplier may be specified in the Framework Agreement, where, as described in the Framework Agreement, the committed volume of medicines is underwritten by the Global Fund.

4. Operational management of PPM orders is described as follows. The Global Fund's selected Procurement Services Agent for antiretroviral and other selected medicines used in HIV programs will perform operational management of the procurement of these medicines under the PPM pursuant to the Framework 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 Framework Agreement.

5. Pursuant to the Framework Agreements, failure to meet performance requirements for quality or delivery or force majeure 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. The Global Fund reserves the right, at its sole discretion, to cap allocated volumes to individual suppliers and to vary these caps between product sets and product categories.

9. 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
    - for each calendar year commencing 2019 to create an incentive pool for subsequent allocation based on the relative performance of the FPP Panel Suppliers in the previous period.
    - for allocation to FPP Panel Suppliers with products with longer approved shelf-life or reduced volume (cartonless) packaging

    If any of the reserved volumes are not utilised, they will be released to existing FPP Panel Suppliers on a six-monthly basis according to performance.

10. There is no minimum allocation to any supplier of antiretroviral and other selected medicines used in HIV programs who is selected as an FPP Panel Supplier, and there is no guarantee that all current suppliers with effective Framework Agreements for the supply of Antiretroviral Medicines will be selected as FPP Panel Suppliers through this RFP.

11. 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 Framework Agreement shall be legally binding.

12. A final agreement with any proposed FPP Panel Supplier is subject to the signing of the Framework 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 Framework 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 Framework Agreement template (Schedule C of RFP) reflects Global Fund's standard terms and conditions. Limited

non-material changes to the Framework 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.

13. As described in the Framework Agreement template (Schedule C 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 Framework 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 Framework Agreement template (Schedule C of RFP), to be finalized as per mutual agreement.
4. The Framework Agreement will include a 'most favoured nation' clause for the benefit of the Global Fund (see Schedule C of RFP for more information).

F. PRODUCT, PACKAGING & QUALITY ASSURANCE REQUIREMENTS

1. All products supplied under this RFP must comply with the following minimum packaging, labelling and quality assurance requirements. These requirements will further be included in each Framework Agreement entered into pursuant to this RFP.

Product and Packaging Requirements

2. The packaging, labelling and accompanying material for each FPP Panel Supplier product (supplier product) shall be in compliance with any applicable laws of the relevant countries, and with the materials and labels approved by the WHO Prequalification Program or Stringent Drug Regulatory Authority (SRA) during the assessment of the said products strictly in line with WHO or SRA Good Manufacturing Process (GMP) Requirements (as the case may be) as well as sound international practices for the packaging and labelling of such supplier product.

3. Supplier products shall be packaged in closed and sealed pharmaceutical storage containers, ensuring that the containers adequately protect supplier products while they are in transit, stored in warehouses or on pharmacy shelves under conditions expected to prevail in the relevant countries.

Quality Assurance Requirements

4. All supplier products must conform to the Global Funds Quality Assurance Policy as defined at https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/.

5. As supplier products will be pre-qualified by WHO or approved by an SRA, the FPP Panel Supplier shall ensure that all supplier products proposed under this RFP will strictly comply with the WHO Prequalification Programme or of the relevant SRA (as the case may be) for

approved products (e.g. manufacturing sites, API source, manufacturing process, specifications, packaging material), WHO or SRA GMP Requirements (as the case may be) and requirements relating to quality, safety and efficacy of the relevant supplier product.

6. Supplier products shall comply with the standards of the current edition of the United States Pharmacopoeia, British Pharmacopoeia, or the International Pharmacopoeia in which the relevant Product Formulations for such supplier products are cited. For any supplier product where the related Product Formulation is not cited in these pharmacopoeias, the supplier product shall comply with the supplier's specifications and validated methods including for safety, quality, and efficacy as submitted to the WHO Prequalification Programme, or the relevant SRA.

7. Supplier products shall comply with the shelf life approved by WHO Prequalification program or by the relevant SRA and for the remaining shelf life with the requirements of the relevant buyer as agreed between the FPP Panel Supplier and the buyer and as specified in the relevant purchase order. The Bidder guarantees that the quality of the supplier products proposed under this RFP will remain the same till the end of the shelf life if stored in a dry space, protected from light and at storage temperatures conforming to the supplier product requirements.

8. Completion of the Officer's Certificate of Conformance and Acknowledgment (Schedule A) shall constitute a representation and warranty by the Bidder that they comply with each of the provisions of this section.

SECTION 5. LEGAL MATTERS

1. By submitting a proposal for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the Bidder agrees to the terms and conditions of all documents mentioned in Section 3A 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 Sections 3A and 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, nor does it commit the Global Fund to pay any cost incurred in the preparation and submission of the proposal(s). Participation in this RFP is subject to the terms and conditions contained herein.

    e. Bidders shall be solely responsible for their own expenses, if any, in preparing and submitting a proposal in response to this RFP. This includes any costs incurred during functional demonstrations and subsequent meetings, workshops and negotiations.

    f. The Global Fund will be under no obligation to reveal, or discuss with any Bidder how a proposal was assessed, or to provide any other information relative to the selection process. Bidders whose proposals are not selected will be notified in writing of this fact, and shall have no claim whatsoever for any kind of compensation.

    g. The Global Fund may, at any stage of this RFP: (a) reject any or all proposals or price submissions; (b) accept for award a proposal or price submission other than the lowest cost proposal or price submission; (c) accept more than one proposal or price submission; (d) accept alternate proposals or price submissions; (e) accept part of a proposal or price submission; (f) waive informalities and minor irregularities in proposals or price submissions received; (g) cancel this RFP.

    h. 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.

    i. 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.

j. 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 and (ii) any other matter relating to procurement of antiretroviral and other selected medicines used in HIV programs 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.

k. 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 antiretroviral and other selected medicines used in HIV programs, 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 antiretroviral and other selected medicines used in HIV programs 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.

l. 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 accorded thereafter.

Schedule A
Officer's Certificate of Conformance and Acknowledgement

*****

Issued Separately

*****

Schedule B
Form of Confidentiality Agreement

*****

Issued Separately

*****

REQUEST FOR PROPOSALS (RFP) TGF-18-010

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

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Issued Separately by 9 February 2018

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

Schedule D
Product segmentation

Product set 1: WHO preferred or alternative regimen products

Item Code	Product Description	Strategic Product
10013	Abacavir/Lamivudine 120/60mg tablet dispersible 30	
10373	Abacavir/Lamivudine 120/60mg tablet dispersible 60	
10015	Abacavir/Lamivudine 60/30mg tablet dispersible 60	
10014	Abacavir/Lamivudine 600/300mg tablet 30	
10022	Atazanavir/Ritonavir 300/100mg tablet 30	
10870	Darunavir/Ritonavir 400/50mg tablet 60	Yes
10871	Darunavir/Ritonavir 800/100mg tablet 30	Yes
10085	Dolutegravir 50mg tablet 30	
10868	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 180 – no carton	Yes
10718	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 30	Yes
10862	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 30 – no carton	Yes
10867	Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet 90 – no carton	Yes
10036	Efavirenz 200mg tablet scored 90	
10040	Efavirenz 600mg tablet 30	
10876	Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 180 – no carton	
10033	Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 30	
10880	Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 30 – no carton	
10875	Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet 90 – no carton	
10874	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet 180 – no carton	Yes
10370	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet 30	Yes
10881	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet 30 – no carton	Yes
10873	Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet 90 – no carton	Yes
10872	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 180 – no carton	
10034	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 30	
10860	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 30 – no carton	
10858	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 90	
10882	Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet 90 – no carton	
10041	Emtricitabine/Tenofovir 200/300mg tablet 30	
10044	Lamivudine/Nevirapine/Zidovudine 150/200mg/300mg tablet 60	
10045	Lamivudine/Nevirapine/Zidovudine 30/50/60mg tablet dispersible 60	
10050	Lamivudine/Tenofovir 300/300mg tablet 30	
10051	Lamivudine/Zidovudine 150/300mg tablet 60	
10052	Lamivudine/Zidovudine 30/60mg tablet dispersible 60	
10062	Lopinavir/Ritonavir 100/25mg tablet 60	
10063	Lopinavir/Ritonavir 200/50mg tablet 120	
10058	Lopinavir/Ritonavir 40/10mg capsule 120	Yes
10090	Lopinavir/Ritonavir 80/20mg/ml oral solution 160ml	
10059	Lopinavir/Ritonavir 80/20mg/ml oral solution 60ml*5	
10066	Nevirapine 10mg/ml oral suspension 100ml	
10067	Nevirapine 200mg tablet 60	
10086	Nevirapine 50mg tablet dispersible 30	
10069	Nevirapine 50mg tablet dispersible 60	

Product set 2: WHO limited use/ specialist products

2a) Low/medium volume

Item Code	Product Description	Strategic Product
10018	Abacavir 300mg tablet 60	
10019	Abacavir 60mg tablet dispersible 60	
10055	Lamivudine 150mg tablet 60	
10070	Raltegravir 400mg tablet 60	
10096	Ritonavir 100mg tablet 30	
10072	Ritonavir 100mg tablet 60	
10077	Tenofovir 300mg tablet 30	
10081	Zidovudine 300mg tablet 60	
10083	Zidovudine 50mg/5ml Oral solution 100ml	
10082	Zidovudine 50mg/5ml Oral solution 240ml	

2b) Very low volume products

Item Code	Product Description	Strategic Product
10017	Abacavir 20mg/ml oral solution 240ml	
10011	Abacavir/Lamivudine/Zidovudine 300/150/300mg tablet 60	
10026	Atazanavir 300mg capsule 30	
10027	Darunavir 600mg tablet 60	
10035	Efavirenz 200mg capsule 90	
10037	Efavirenz 200mg tablet 30	
10883	Efavirenz 200mg capsule 30	
10884	Efavirenz 200mg tablet 90	
10866	Efavirenz 30mg/ml Oral solution 180ml	
10038	Efavirenz 50mg capsule 30	
10039	Efavirenz 50mg tablet 30	
10865	Emtricitabine 10mg/ml Oral solution 170ml	
10089	Etravirine 100mg tablet 120	
10864	Etravirine 200mg tablet 60	
10053	Lamivudine 10mg/ml oral solution 100ml	
10375	Lamivudine 10mg/ml oral solution 240ml	
10032	Lamivudine/Zidovudine+Efavirenz 150/300+600mg 60+30 tablet co-blistered 90	
10885	Tenofovir 40 mg/g granules - 60g	

2c) Not procured in 2016-2017

Item Code	Product Description	Strategic Product
10024	Atazanavir 150mg capsule 30	
10023	Atazanavir 150mg capsule 60	
10025	Atazanavir 200mg capsule 60	
10320	Darunavir 150mg tablet 240	
10317	Darunavir 400mg tablet 60	
10319	Darunavir 75mg tablet 480	
10318	Etravirine 25mg tablet 120	
10047	Lamivudine/Tenofovir+Atazanavir+Ritonavir 300/300+300+100mg tablet co-blistered 60	
10322	Raltegravir 100mg Tablet Chewable 60	
10323	Raltegravir 25mg tablet chewable 60	
10073	Ritonavir 80mg/ml oral solution 90ml	
10887	Ritonavir 100mg powder for oral solution - 1 sachet	
10078	Zidovudine 100mg capsule 100	
10886	Zidovudine 10mg/ml injection for infusion 20ml – 5 ampoules	

Product set 3: Other Selected Medicines used in HIV Programs

Item Code	Product Description	Strategic Product
	Daclatasvir tablet 30mg	Yes
	Daclatasvir tablet 60mg	Yes
	Sofosbufir tablet 400mg	Yes
	Sofosbuvir/ Ledipasvir tablet 400mg/90mg	Yes
	Sofosbuvir/ Daclatasvir tablet 400mg/60mg	Yes
	Sofosbuvir/Velpatasvir tablet 400mg/100mg	Yes
	Entecavir tablet 0.5mg scored	Yes
	Entecavir tablet 1mg scored	Yes
	Isoniazid 100mg	Yes
	Isoniazid 300mg	Yes
	Isoniazid/cotrimoxazole/vitamin B6 300/960/25mg	Yes
	Flucytosine capsule 250mg	Yes
	Flucytosine capsule 500mg	Yes
	Flucytosine tablet 250mg	Yes
	Flucytosine tablet 500mg	Yes
	Flucytosine injection 10mg/ml	Yes
	Amphotericin B injection Deoxcholate 50mg	Yes
	Amphotericin B injection Liposomal 50mg	Yes
	Pergolated liposomal doxorubicin 2mg/ml 20mg vial	Yes
	Pergolated liposomal doxorubicin 2mg/ml 50mg vial	Yes

Schedule E
Response Templates

These are presented as three separate Excel Files:

- E1: Technical
- E2: Commercial
- E3: For Information and Implementation

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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 calandar year 2018 based on information available as of 31 January 2018. Overall volumes are not anticipated to be lower in subsequent calandar 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 and for Product Set 3 with limited or no demand visibility.

Number of packs 2018		
Efavirenz/Lamivudine/Tenofovir 600/300/300mg tablet Efavirenz/Lamivudine/Tenofovir 400/300/300mg tablet Efavirenz/Emtricitabine/Tenofovir 600/200mg/300mg tablet Dolutegravir/Lamivudine/Tenofovir 50/300/300mg tablet	*may be procured in various sizes but expressed as packs of 30 for forecasting purposes*	42,000,000
Lamivudine/Nevirapine/Zidovudine 150/200mg/300mg tablet 60		4,000,000
Lamivudine/Tenofovir 300/300mg tablet 30		2,000,000
Efavirenz 600mg tablet 30		2,000,000
Lamivudine/Zidovudine 150/300mg tablet 60		1,600,000
Lamivudine/Nevirapine/Zidovudine 30/50/60mg tablet dispersible 60		1,500,000
Abacavir/Lamivudine 120/60mg tablet dispersible (expressed as packs of 30)		1,000,000
Atazanavir/Ritonavir 300/100mg tablet 30		700,000
Lopinavir/Ritonavir 200/50mg tablet 120		650,000
Nevirapine 200mg tablet 60		550,000
Abacavir/Lamivudine 600/300mg tablet 30		500,000
Emtricitabine/Tenofovir 200/300mg tablet 30		400,000
Lamivudine/Zidovudine 30/60mg tablet dispersible 60		400,000
Lopinavir/Ritonavir 100/25mg tablet (expressed as packs of 60)		400,000
Abacavir/Lamivudine 60/30mg tablet dispersible 60		250,000
Nevirapine 10mg/ml oral suspension 100ml		250,000
Dolutegravir 50mg tablet 30		150,000
Efavirenz 200mg tablet scored 90		135,000
Nevirapine 50mg tablet dispersible (expressed as packs of 60)		100,000
Lopinavir/Ritonavir 40/10mg capsule 120 (demand constrained estimate)		85,000
Abacavir 300mg Tablet 60		40,000
Zidovudine 50mg/5ml Oral solution 100ml		35,000
Lamivudine 150mg tablet 60		35,000
Tenofovir 300mg tablet 30		35,000
Lopinavir/Ritonavir 80/20mg/ml oral solution 60ml*5		30,000
Ritonavir 100mg Tablet (expressed as packs of 60)		15,000
Zidovudine 300mg Tablet 60		10,000
Efavirenz 50mg tablet/capsule 30		10,000
Darunavir 600mg Tablet 60		10,000
Abacavir 60mg tablet dispersible 60		5,000
Lamivudine 10mg/ml oral solution 100ml		2,500
Others		102,500
Total packs (all products)		59,000,000