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Subject: REQUEST FOR PROPOSAL (RFP) TGF-14-040

ANTIRETROVIRAL MEDICINES (ARVs)

Through this Request for Proposal (“RFP”), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the “Global Fund”) invites all potential bidders to submit proposals to supply Antiretroviral Medicines (“ARVs”) for delivery during calendar years 2015 to 2017 to recipients of Global Fund financing, as fully described in this RFP.

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1. Introduction

1.1 Objectives

- 2.4 The purpose of this RFP is to select a panel of suppliers who will enter into Framework Agreements (long-term agreements) with the Global Fund to supply ARVs procured with Global Fund financing through the Pooled Procurement Mechanism (“PPM”, formerly referred to as Voluntary Pooled Procurement).

Framework Agreements will be of two types determined by the volume of products supplied and the Global Fund evaluation of submitted proposals.

Type 1: Supplier Partnerships: Shall be for a term of up to three years and renewable for a further period of up to two years thereafter. Agreements will comprise initial aggregated demand for the PPM countries - both allocated and committed volumes for 2015 and 2016 and a forecast for 2017. Thereafter forecasts will transfer into allocated and committed volumes on an annual basis. 2015 and 2016 volumes will be established at the time of Framework Agreement signature and 2017 volumes are expected to be established in quarter 3 2015.

Type 2: Supply Agreements: These Framework Agreements will be for a term of up to two years covering calendar years 2015 to 2016, comprising both allocated and committed volumes for each year, determined on an annual basis. 2015 volumes will be established at the time of Framework Agreement signature, and 2016 volumes are expected to be established in quarter 2 2015.

ARVs not listed or that cannot be supplied under this RFP (e.g. due to licensing or intellectual property limitations) will be purchased on an individual purchase order basis

1.2 Structure of RFP and Award

1. The RFP and award process will take place in two Stages:
 - a. **Stage 1** involves the preparation, submission and opening of proposals, preliminary examination and evaluation of proposals, and the invitation of individual bidders that submitted responsive proposals (the “Qualified Bidders”) to participate in Stage 2. Invitations to stage 2 will also include a list of specific priority topics for discussion.
 - b. **Stage 2** involves an evaluated workshop where the supplier has the opportunity to discuss more detailed information on the submitted Development Road-Map (Schedule B3) as directed by the Global Fund’s invitation and the Global Fund has the opportunity to clarify aspects of the overall proposal. Bidders who are not invited to participate in workshops will be requested to take part in one round of negotiation, preferably by phone for any clarifications and finalise both the commercial and non-commercial elements of the proposal.
2. Following Stage 2 the final decision on allocated and committed volumes will be made by the Global Fund and communicated to all Qualified Bidders. These final decisions will be based on the evaluation approach as detailed in Section 3 of this RFP. Any agreement between the Global Fund and a Qualified Bidder shall be reflected in the terms and conditions of a definitive agreement with such Qualified Bidder.

1.3 *Timeline of RFP*

- Proposals must be submitted by **12 September 2014, 17.00hrs Geneva Time**
- The scheduled time of the key activities of this RFP are as follows, with all times Central European Time (Geneva):

Activity	Scheduled Time – Deadline
1. Request for Proposal issued	25 July 2014 17.00hrs
2. Deadline for prospective bidders to submit Round 1 requests for clarification by email to the RFP and the proposal contract	8 August 2014 17.00hrs
3. Last day for the Global Fund to issue responses to all Round 1 requests for clarification to all prospective bidders	15 August 2014
4. Deadline for prospective bidders to submit Round 2 requests for clarification by email to the RFP and the proposal contract	22 August 2014 17.00hrs
5. Last day for the Global Fund to issue responses to all Round 2 requests for clarification to all prospective bidders	29 August 2014
6. Deadline for electronic submission proposals	12 September 2014 17.00hrs
7. Stage 1 Examination and evaluation of proposals	15 September – 3 October 2014
8. Issuance of invitation for Stage 2 to Qualified Bidders who have been selected for participation in either collaborative workshops or a second round of negotiation.	6 October 2014 17.00hrs
9. Scheduled Dates for Stage 2, Collaborative Workshops in Bangalore, India (alternate locations for non-Indian-based suppliers either before or after this week in Geneva or as mutually agreed)	13-17 October 2014
10. Final evaluation and volume allocation including additional time for second round negotiations for those not participating in workshops.	20-31 October 2014
12. Notification of Awards to Bidders	Anticipated by 20 November 2014

1.3 *Conditions for RFP Participation*

- Only bidders with products in compliance with the Global Fund Quality Assurance Policy on Pharmaceuticals are eligible to participate in this RFP as a Bidder (see <http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#General>), and all products supplied pursuant to this RFP must comply with those requirements.
- A Bidder 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 (2013, as amended from time to time), in order to be eligible as a supplier to the Global Fund. The Code of Conduct for Suppliers and the Sanctions Procedures Relating to the Code of Conduct for Suppliers are available on the Global Fund's website at the following link:
<http://www.theglobalfund.org/en/library/documents/>.
- Participation in this RFP is subject to the terms and conditions contained herein. 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).

4. All proposals must remain valid for a period of 120 calendar days from the deadline for the electronic submission of proposals.
5. A bid security is not required for proposals submitted under this RFP.
6. 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 <http://www.theglobalfund.org/en/business/solicitations/>. 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.
7. 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.
8. The Global Fund will be under no obligation to reveal, or discuss with any Bidder or supplier, how a proposal or price submission 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.
9. The bidders shall not be required to quote for all products. However, bidders are encouraged to quote for as many products as possible.
10. 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.
11. By participating in this process, Bidders agree to the legal terms and conditions in Section 6.

2. Scope of the RFP

2.1 *The Global Fund's ARV Procurement Strategy*

1. The Global Fund has adopted a new model for the procurement of Antiretroviral Medicines (ARVs) based on the principles detailed in the Global Fund Strategic Framework 2012-2016 'Investing for Impact'.¹
2. In developing the ARV procurement strategy, the Global Fund has determined the following key specific objectives to support the core ambition of increasing access to quality assured products at the optimum price while simultaneously maintaining a sustainable, competitive market. These principles are based on a combination of

¹ <http://www.theglobalfund.org/en/about/strategy/>

analysis of recent market dynamics data and discussions with manufacturers, our recipients, donors and other technical agencies. The principles are:

- a. The maintenance of a sustainable and predictable supply of the full range of the needed products at each stage of their lifecycle.
- b. Improvements to supply chain integrity by de-risking the supply of active pharmaceutical ingredients (API) and key starting materials (KSM).
- c. The provision of increased visibility through better forecasting and a reduction in costs by streamlining administrative processes.
- d. Ensuring continuous reliable supply through a reduction in lead times, improved supplier delivery performance and where possible the mitigation of force majeure.
- e. Underwriting affordability by ensuring competitive pricing through the use of supplier engagement strategies based, where applicable on the principle of strategic partnerships.
- f. Maintaining sufficient supplier presence in the market by understanding and supporting adequate returns to enable forward investment and by encouraging new entrants who can demonstrate sufficient value add to the program.
- g. Enabling a quicker introduction of new products (in partnership with technical agencies through the provision of more targeted, reliable and timely product pipeline information).
- h. Encouraging the development of products with longer shelf life and widespread country registration to reduce supply chain risks.
- i. Working with originator and generic manufacturers to facilitate the development and scale-up of new optimal products as recommended by WHO.

2.2 Strategy Execution

To execute the strategy the Global Fund has analysed the product set against a lifecycle model and had defined different priorities for products at different stages within this. As products transition through the lifecycle the Global Fund's priorities change with sustainable supply becoming an increasing priority especially for declining or legacy products. It should however be emphasised that affordability and delivery performance remain a priority at each stage. The full model as shown at Schedule E and was also shared at the ARV Supplier Conference, Dubai, June, 24th -25th 2014.

To underwrite this approach the Global Fund wishes to form long-term strategic partnerships with selected suppliers who 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. Resulting value will be shared between parties through mutual agreement.

The Global fund also recognises that this model may not be appropriate in all cases and will, in parallel, offer shorter-term contracts or procure through a Purchase Order (PO) including with other suppliers, whichever is more feasible to ensure affordability and supply chain integrity.

2.3 Product Segmentation

To facilitate analysis and RFP management ARV products have been segmented both horizontally by product type and vertically by their stage in the product lifecycle.. The indicative historic spend shown in this table is for information purposes only and the volume (where known) against which bidders should be submitted is shown at Schedule F.

Certain products have also been labelled ‘High Risk’ which indicates that challenges may have occurred or be expected in obtaining sufficient volumes in an appropriate timescale. The impact of this flag on the evaluation process is shown in Section 3.6 of this RFP.

Other products are labelled as “High Opportunity Optimal Products or Formulations” where volumes may be currently small and pricing higher than it could be if volumes were larger.

Overall, Bidders are requested to propose innovative and achievable pricing and discounts. For ‘High Opportunity’ products they are also requested to indicate threshold volumes for price reductions. This is explained in Schedule B1.

Classification	Type	PPM historic spend 2013 and Q12014	No of Products
Adult Optimal NRTI and NNRTI High Volume 1 st and 2 nd Line	TDF FDCs	\$280m	4
	AZT FDCs	\$137m	2
	EFV 600mg NVP 200mg	\$19.5m	1 1
Adult Optimal NRTI and NNRTI Low Volume		\$13.7m	14
Adult Optimal Pls (2 nd Line)		\$30.4m	5
Adult 3 rd line		\$1.6m	3
Adult Legacy Products		\$2.8m	14
Paediatrics: IATT ² Optimal Products		\$10.6m	10
Paediatrics: IATT Limited Use Products		\$0.8m	12
Paediatrics: IATT Non-Essential products (including legacy products)		\$2.5m	42

Vertical Segmentation defines where, in the Global Fund’s opinion (which is final), individual products are in their own lifecycle. This segmentation serves to allow bidders to determine the Global Fund’s commercial priorities and structure their response accordingly.

A full product database has been supplied in Excel format at Schedule F that shows both the vertical (lifecycle) and horizontal (product classification) segmentation for all the products within the scope of this RFP.

² The IATT classification relates to recommendations made by the Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and their Children of currently available preferred and alternative drugs as detailed in the WHO’s 2013 Consolidated Guidelines. The details can be found at

- WHO March 2014 supplement to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection [<http://www.who.int/hiv>]
- Update to the optimal list of paediatric ARV formulations, IATT [<http://www.emtct-iatt.org>]

2.4 Product Volumes

1. The total forecasted volume of products covered by this RFP shall comprise the total forecasted demand through the Pooled Procurement Mechanism as shown as a worksheet within Schedule F.
2. There is no forecasted volume for allocation through the Rapid Supply Mechanism (as defined and discussed below) in this RFP, however, bidders final price submissions for PPM product will also apply to RSM product when and if procured by the PSA.

2.5 Contracting

3. Through this RFP, allocated volumes of ARVs will be made to a panel of suppliers who will be invited to enter into Framework Agreements which will either be a Supplier Partnership of duration of up to three years and potentially extendable by a further two years or a Supply Agreement of duration of two years. The Framework Agreements will provide for the following ARV volume arrangements:
 - a. A committed volume for each Panel Supplier where the number of ARVs is underwritten by the Global Fund; and
 - b. An allocated volume directed towards specific Panel Suppliers, but which requires further grant management activity and is not underwritten by the Global Fund.

2.6 Supplier Management

1. The Global Fund reserves the right to cap allocated volumes to individual suppliers and to vary these caps between lifecycle segments.
2. For products in certain lifecycle segments, the Global Fund will ensure a proportion of available volumes will be left open for subsequent negotiation with manufacturers of newly qualified products according to the Global Fund Quality Assurance Policy (reference section 1.3) for possible entry into the market. If no new entrants emerge, this volume will be released to existing panel suppliers on a six monthly basis according to performance.
3. Volume percentages left open by lifecycle stage are as follows:
 - a. Emerging, Growing, Mature: 20%
 - b. Declining: 0%.
4. There is no minimum allocation to any supplier of ARVs who is selected as a Panel Supplier, and there is no guarantee that all current suppliers of ARVs will be selected as Panel Suppliers through this RFP

2.7 Contract Management

1. The Global Fund's selected Procurement Services Agent for ARVs, currently the Partnership for Supply Chain Management (PFSCM), will perform operational management of the procurement of ARVs under the PPM pursuant to the Framework Agreements entered into between Panel Suppliers and the Global Fund, including the placement of purchase orders, monitoring of supplier performance, and tracking of purchases that count towards the Global Fund's volume commitment. The current PPM Master Supply Agreements between suppliers and PFSCM (where applicable) will be replaced by new Framework Agreements between the supplier concerned and the Global Fund.
2. 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 Panel Suppliers, removal from the supplier Panel, or inclusion of suppliers outside the Panel. Further, if a 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 committed volumes.

2.8 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. Subsequent collaborative working arrangements may require further granularity.
2. For Suppliers who sign either type 1 or type 2 framework Agreement, pricing will be reviewed between the Global Fund and individual suppliers as part of the annual 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 will also consider the implementation of a price adjustment mechanism and bidders are invited to submit their proposals for such a mechanism at Schedule B1. This will subsequently be discussed during the negotiation process and, if implemented, finalized in the framework agreements.
4. The Global Fund intends to offer access to the base prices, i.e. without the discounts and other terms related to the framework agreements to non-PPM countries and other agencies. The access to these pricing will be subsequently agreed between parties and defined in the Framework Agreement.
5. The Framework Agreement will include a 'most favoured nation' clause for the benefit of the Global Fund (see Schedule C for more information).

2.9 Rapid Supply Mechanism (RSM)

1. The Global Fund will be establishing a Rapid Supply Mechanism to increase its capability to respond to urgent demands for critical health products, including ARVs, to its grant recipient countries.

2. Various options are being considered for the provision of this capability for a range of product categories, for example, establishing a stockpile in a designated warehouse or having agreements with suppliers on Vendor Managed Inventory (VMI), or a combination of options.
3. A specific section of Schedule B2 relates to the RSM and within this suppliers are requested to present suggestions and feasibility of vendor managed inventory for some or all products. Submitted proposals will be not be evaluated as part of the technical submission and are for information only. Detailed volumes are as yet unknown.

3. Instructions to Bidders and RFP Process

3.1 Overall Process

1. The RFP process will take place in two Stages, as indicated in Section 1.2 of this RFP.
2. The Global Fund shall 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 shall be declared late, rejected, and returned unopened to the Bidder concerned.
3. 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 (see Schedule H) and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2012, as amended from time to time).
4. During the evaluation of proposals, the following definitions apply:
 - a. "Deviation" is a departure from the requirements specified in this RFP;
 - b. "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in this RFP; and
 - c. "Omission" is the failure to submit part or all of the information or documentation required in this RFP

3.2 Communications during the RFP

1. This RFP is in two stages, 1) proposals submission and 2) face to face evaluated workshops or teleconference for 2nd round negotiations, with stage 1 being managed electronically. Potential bidders are required to submit their proposals by e-mail to solicitation@theglobalfund.org, clearly indicating the supplier's name and the RFP number in the subject line of the e-mail.
2. All communications with regard to this RFP, i.e. for both stage 1 and 2 shall be through the following single point of contact at the Global Fund:

Mme. Anne-Sophie Salmon
Sourcing Manager, Sourcing Department
anne-sophie.salmon@theglobalfund.org.

3. Any communication between a Bidder and the Global Fund regarding this RFP, made between the Issue Date and the Notification of award, which is not through the channel designated in this Section 3.2, shall invalidate the Bidder's proposal to this RFP.

3.3 Confidentiality

1. 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.
2. 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.
3. The Global Fund also recognises 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 C.

3.4 Stage 1: Preparation and Submission of Proposals

1. Each Bidder shall complete three templates, and each template (which comprises a number of sheets in a single workbook) has its own accompanying notes.
 - Schedule B.1 The Global Fund ARV Proposal Template: Evaluated Elements, Commercial and Technical.
 - Schedule B.2 The Global Fund ARV Proposal Template: Request for Information
 - Schedule B.3 The Global Fund ARV Proposal Template: Development Road Map
2. Each proposal template is an Excel workbook that contains general instructions on the first Worksheet and specific instructions for each question.
3. Bidders may offer products either on a company wide basis or specifically from individual operating entities. However those who wish to offer products from more than one operating entity shall complete separate templates for each.
4. Bidders are expected to fully respond to all the questions or provide the relevant information as required. Failure to do so will be considered not fully responsiveness at the stage 1 evaluation, and will be taken into account in the selection for evaluated workshops and/or Partnership Agreements and/or the overall evaluation.
5. All Stage 1 proposals shall be submitted electronically using either the three pre-formatted templates or the alternative detailed at Section 3.6.11 of this RFP. All documents are to be submitted as separate files with each file not exceeding 8mb. Each proposal shall be submitted in both of the following formats to ensure no errors occur in the evaluation process:
 - a. A signed copy of all submissions in PDF format, where all copies shall be legible; and
 - b. A duplicate copy of all documents, in either Microsoft Word, Excel or PowerPoint format, as the case may be. If bidders submit responses to Schedule B3 in the form

of work plans prepared using proprietary software these are required in pdf format only.

In the event of a conflict between the signed copy and the duplicate copy, the signed copy shall govern.

6. All proposals shall conform to the following conditions:
 - a. All proposals shall be written and submitted in the English language;
 - b. All products must be described in the format used in the Product Database and it is recommended that bidders cut and past these names into the templates as and when required.
 - c. All prices shall be quoted in US Dollars; and
 - d. All product prices as required in Schedule Bi Section 1.1 shall be quoted Ex-works (Incoterms 2010).
7. Proposals shall include a completed Officer's Certificate of Conformance and Acknowledgement, as contained in Schedule A and confirmation of workshop availability using the template at Schedule J.
8. When submitting their proposals bidders are requested to include in their covering email a complete list of the files submitted.

3.5 Background and Specific Instructions Relating to Schedule B3: The Development Road Map.

1. All schedules have instructions for their completion within the Excel workbook however to provide bidders with additional background and to assist with completing Schedule B3 (which is only required if the answer to Q1 in Schedule B1 is 'yes') these additional notes are provided.
2. The Development Road Map is designed to provide the initial structure around which the Global Fund can form its supplier partnerships to support through life product management.
3. Experience from other sectors indicates that, to be successful, partnerships must be goal orientated, have a defined governance model and take into account the incentives and needs of both parties.
4. The Development Road Map has been designed to reflect these principles and Bidders are requested to identify a series of objectives and for each to then complete a set of questions designed to add further detail.
5. The objectives should be designed to create value and it is the intention that, where possible, this value will be shared between the Global Fund and the respective supplier.
6. The definition of value is broad, the strategy defined in Section 2.2. has many goals and the objectives defined should reflect these. This may include, but not limited to the list below and any value-creating objective is encouraged and will be considered.
 - a. Reductions in cost through process improvement, volume manufacture, greater supply chain efficiency, improved yields, different order placement, forecasting and payment structures - or for any other reason.

- b. Reduced risk through diversification and other measure to achieve security of API supply and the introduction of new raw material sources.
 - c. Actions to improve supply chain integrity particularly of low volume, legacy paediatric ARVs identified as high risk products including proposals for time-limited exit strategies/vendor managed inventory
 - d. Proposals to reduce or remove price differentials for improved formulations especially of optimal paediatric ARVs identified as high opportunity products (e.g. for dispersible and/or scored tablets)
 - e. Improved product shelf life and broader national registrations.
 - f. Actions to expedite new product introduction allowing more focused investment including, after WHO endorsement, accelerating the availability of formulations with lower doses of ARV components with the view to both lower cost but also improve safety profiles
 - g. Targeted improvements to supplier delivery performance and actions to underpin this.
 - h. Proposal to simplify or improve packaging to reduce costs of the product or logistics; or to support improved patient compliance
7. In addition to these objectives the Global Fund has also identified some specific product related objectives and proposals related to these would also be welcome as part of your submission in Schedule B3.

Product	Objective
Abacavir+ Lamivudine, 60 mg + 30 mg Tablets for oral suspension	Reduction in price premium over non-dispersible product.
Efavirenz 200 mg Tablet scored	
Lamivudine + Zidovudine 30 mg + 60 mg Dispersible Tablet	
Lamivudine + Nevirapine + Stavudine 30 mg + 50 mg + 6 mg Dispersible Tablet	Proposals with time-limited/capped ethical exit strategies/VMI related to Paediatric ARV Procurement Working Group (PAPWG) coordinated procurement
Lamivudine + Stavudine 30 mg + 6mg Tablet for Oral Suspension	
Didanosine 200 mg Capsule Delayed release	
Didanosine 125 mg Capsule Delayed release	
Didanosine 25 mg chewable tablet	

8. Each objective must have a defined measurable benefit. This does not necessarily need to be expressed in financial terms. For instance increasing the shelf life of specified products from 24 to 36 months in May 2015 is both defined and measurable. However for benefit sharing to be effective a number of financial objectives should be included.
9. Each objective must be directly related to the supply of ARVs that are the in the scope of this RFP or pipeline products currently in the pre-qualification process or related to the specific products detailed above.

10. Bidders are advised to propose a combination of both short term (less than 6 months) and long term objectives, as early success will build credibility.
11. The total number proposed is entirely at individual discretion but bidders are advised to limit their detailed proposals to maximum 10 initial objectives, of which at least 50% must not be related to the specific products detailed in Para 7. Space is available to highlight other concepts, which may be no more than 'ideas' at the time of submission.
12. For each detailed objective proposed bidders are also requested to complete the following details:
 - a. Objective Definition, Criteria for measuring success, Initial Target and Target Date.
 - b. Sponsor, Team members, Proposed management structure including periodicity of team meetings. (It is recognised that this may be the same across a number or, all objectives).
 - c. External support required from both the Global Fund and other agencies.
 - d. Where applicable the proposed benefit share between the Global Fund and the Supplier and the level of confidentiality required between parties.
13. A formatted timeline is also provided where bidders are requested to identify the specific work streams required to achieve the objective, the key activities and duration of each and the key milestones.
14. A 'worked example' of an objective is provided at the beginning of Section B3.
15. The template is designed to identify the information required and to enable bidders without project management software to provide an interpretable response. However the Global Fund will accept responses in alternative formats (for instance a Word document and a project management template or a word document and the template in Schedule B3) provided the following criteria are adhered to:
 - a. All the questions for each objective in Schedule B3 are answered under a separate heading.
 - b. Work plans developed using proprietary software are only submitted in pdf format ensuring that they are clearly readable.
16. The process for evaluating the template both initially and in subsequent workshops is described in Sections 3.7 and 3.8

3.6 Stage 1: Examination and Evaluation of Proposals

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. The overall process for Stage 1 shall be as follows:
 - a. Bidders shall submit the documents as defined in Section 3.5
 - b. The Global Fund will conduct a preliminary scored evaluation and completeness assessment on Schedules B1 and B2.
 - c. Schedule B3 will be subject to an initial assessment to determine that it has been completed with areas for further investigation and clarification and the potential for forming a strategic partnership.
 - d. Following the initial evaluation and assessment selected bidders will be invited to participate in Stage 2 and will be advised whether they will be offered a workshop session based on the preliminary evaluation of Schedule B1, submission of schedule B2 and B3 and their own willingness to participate or whether they will be invited for a phone call to participate in a second round of negotiations.

2. The evaluation criteria for Stage 1 for Schedule B1 will be as shown below and for this RFP, there will be one evaluation combining both technical and commercial proposals. 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.

3. The overall weighting of the combined Commercial and Technical Evaluation for stage 1 will be 55%, while that of the Development Road Map (which is only evaluated at stage 2) will be 45%.

Element	Criteria	Use by Evaluation Team	Overall Weighting
Evaluated Commercial and Technical Criteria, please refer to Schedule B1			
Commercial Approach	Bidders to indicate whether or not they wish to be considered for a strategic supplier partnership	Evaluated	Evaluated criteria comprise 55% of the overall ranking
Product Information and Regulatory Approvals	Eligible products and approved packaging, formulation, strength, manufacturing site(s). Date of pre-qualification, approved shelf life(s). Inclusion of syringe for oral solutions	May be validated; evaluated	
Value added dosage form features	Emphasising formulation features such as dispersible, scored etc		
Registered API Sources in in Current Dossier	Details for each API	May be validated; evaluated	
Product Cost	API Cost per Kg Cost of non-active ingredients Yield % Conversion Cost Overhead Cost Total Bulk Cost Packaging Cost Syringe for oral solutions	May be validated; For information and potential input to phase 2 including road map development	
Sales price per Pack (base price)		Evaluated	
Premiums for Country Customised Packaging (or reversed as a discount for universal packaging/labelling – see below under discounts)	Requirement Details Required Countries Premium Price per pack	Evaluated	
Discounts	Discounts offered – for example: volume;; bundling of products,, universal packaging/labelling etc. and additional criteria required to activate the discounts	Evaluated	
Quality and Delivery Performance	Historical quality and on time performance. (From historic PPM internal data. Format is shown for information in Schedule B2	Evaluated	
Price Risk Identification and Mitigation	Proposals for the mitigation of risk in elements of the pricing	Evaluated	

Element	Criteria	Use by Evaluation Team	Overall Weighting
Request for Information (Please refer to Schedule B.2) <ul style="list-style-type: none"> All elements may be used as a potential input to phase 2 including road map development The Global Fund reserves the right to request supporting documentation to validate the supplied information and to validate it through other sources There will be a continuing obligation to keep the Global Fund updated of any changes in this information throughout the duration of the contract period in a format to be advised by the Global Fund.			
Company Details	Name, Address Contact Details	For information	
Manufacturing Address	Full manufacturing address / approved sites and manufacturers abbreviation	May be validated	
Product Pipeline (WHO Prequalification and/or Stringent Authority approved)	Product, applicant manufacturing site, packaging, filing date, WHO PQ confirmation date, estimated approval date, shelf life, API sources	May be validated For Information	
Country Registration	Registered products by country	May be validated For information and to support the allocation process	
Licensing	Licensing scope detailed by country	May be validated For information and to support the allocation process	
Committed Production Capacity	Manufacturing site, batch size, maximum committed monthly output, capacity and substitutability, lead time, indicative lead time for country specific packaging	May require validation For information to assess feasibility of response; to support workshop selection; and the allocation process	
Output History	Lead times and actual outputs 2013 and 2014	May require validation For Information to assess feasibility of response to support workshop selection; and the allocation process	
Additional Information	Overview of ARV strategy Description of API strategy and steps to secure API/FDF supply Description of approach to licensing Suggestions and feasibility to support the RSM in the medium term through vendor managed inventory	For Information For Information For Information For Information and potential further exploration	

4. The Global Fund shall evaluate the proposals as follows:

- a. Commercial and Technical 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. Bidders are

advised that the following criteria (which are not in order of priority) will be included in the evaluation.

- i. Completeness of data / information provided
 - ii. Overall cost
 - iii. Scope of approved products that are included in price submissions
 - iv. Ability to supply 'At Risk' products
 - v. Ability to supply "High Opportunity Optimal Products or Formulations"
 - vi. API Supply chain risk
- b. Request for Information. Individual elements are not evaluated but completion is required in accordance with section 2 above and may be used or validated by email/telephone call or in the workshops.
5. The Global Fund will review the results from the initial submissions and determine which Bidders will be eligible for submission for either type 1 or type 2 agreement indicated below for the Stage 2.
6. Selection for stage 2 workshops will be based on the following evaluated criteria:
- i. Bidders willingness to participate
 - ii. Historic spend and value of products for which proposals have been submitted.
 - iii. Range and type of products offered (including low volume products)
 - iv. Available manufacturing capacity across all products bid.
 - v. Price including any discounts offered
 - vi. Potential value demonstrated in submitted Road Map
 - vii. Number of lifecycle segments included in the overall proposal.
7. The Stage 2 notification will include the following information.
- a. Proposed route for stage 2 finalization and proposed type of framework agreement.
 - b. If Type 1: Supplier Partnership, proposed time, place and duration of evaluated collaborative workshop.
 - c. Specific areas for further investigation and priority topics for the workshop.
 - d. If Type 2: Supply Agreements, arrangements for the final round of discussion and opportunity for Suppliers to submit best and final offers.

3.7 Stage 2: Procedures

1. The following process will be adopted for the management of collaborative workshops.
 - a. The workshop will take place at the time and place and for the duration advised in the notification process. Approximately 5-6 participants from the Global Fund will attend and Bidders are requested to ensure participation of relevant parties to ensure the meaningful discussion envisaged (including on the technical aspects of some of the proposed projects), but limit their own attendance to a maximum of 10 participants.
 - b. While no specific format is prescribed, the Global Fund anticipates that bidders will provide a brief overview of their Road Map and responses to the specific points raised in the Stage 2 notification. Time for each section will be agreed up front and the Supplier may suggest an agenda beforehand.

- c. Global Fund will also identify any aspect of the stage 1 proposal including negotiations on bundles that requires further discussion, and the relevant aspects / topics for discussion will be included in the Stage 2 notification
 - d. Adequate time should be set aside for a discussion of the proposal by both parties.
 - e. At the conclusion of the discussion both parties will confirm the points that have been agreed and those where further deliberation is required on the part of the supplier.
 - f. As soon as practicable after the workshop the Global Fund will confirm to the Supplier the points agreed and those requiring further deliberation.
 - g. The Supplier is then requested to re-submit within an agreed timescale their Road Map and/or Schedule B1 including the confirmed points and the results of their own deliberation. This submission will form their Best and Final Offer (**BAFO**).
2. For bidders who are not invited to participate in a collaborative workshop for the Stage 2 will be invited for one round of further clarification and negotiation conducted either face to face or by telephone. Following this, these bidders shall be requested to submit their BAFO.

3.8 Stage 2 Evaluation

1. For bidders who attend collaborative workshops the Stage 2 evaluation combines an analysis of the final submission of the Development Road Map together with a capability analysis derived from the Global Fund's workshop experience. Bidders will be ranked in order of the evaluated scores, using a normalization algorithm to score bidders relative to each other.
2. The following evaluation criteria shall be used (which are not shown in a specific order)
 - a. By Objective
 - i. Total Value offered and timeline to deliver
 - ii. Ability to deliver and associated risks
 - b. By Supplier
 - i. Structure of Governance model including project management methodology
 - ii. Level of commitment and Sponsorship.
3. The Global Fund reserves the right to update Schedule B1 in the light of any clarifications or facts learnt in the workshop regarding any evaluated criteria.
4. For bidders who have been requested to submit a BAFO against Schedule 3.1 either as part of the collaborative workshop or from a second round negotiation the revised information will be re-evaluated using the same processes as defined in Section 3.6.
5. The scores from the evaluated workshops or teleconferences and Schedule B1 will then be combined to provide the overall ranking.
6. The Stage 2 evaluation will conclude with the production of a final list of Qualified Bidders, ranked by their relative and comparative performance against the evaluated criteria.

4. Volume Allocation and Initial Contracting

4.1 Volume Allocation

1. The allocation of product volumes of ARVs by the Global Fund to selected Qualified Suppliers is conducted at the end of the Stage 2 evaluation process and is described here for information purposes only.
2. The Global Fund will allocate product volumes (including committed volumes) using the following process:
 - a. An initial allocation will be achieved by distributing the total committed volume among successful bidders in proportion to their relative scores and subject any overall caps imposed;
 - b. The initial allocation will then be validated against the following criteria, as applicable, and may be adjusted to achieve the most effective fit:
 - i. Available Committed Capacity;
 - ii. Range of Products Proposed
 - iii. Country Registration.

4.2 Notification on Selection and Decision of Allocation of Product Volumes

1. Upon and subject to successful completion of the RFP process, the Global Fund intends to notify selected Panel Suppliers and the proposed volume commitments by 20 November 2014.
2. A final agreement with any proposed Panel Supplier is subject to a definitive written agreement between that Supplier and the Global Fund. If the Global Fund and a proposed 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 Form of 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 Panel Supplier.

5. Product, Packaging, and Quality Assurance Requirements

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.

5.1 Product and Packaging Requirements

1. The packaging, labelling and accompanying material for each supplier product shall be in compliance with any Applicable Laws of the relevant countries, and with the materials and labels approved by WHO prequalification Program or Stringent Regulatory Authority during the assessment of the said products strictly in line with World Health Organisation (WHO) or Stringent Drug Regulatory Authority (SDRA), 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.
2. 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.

5.2 Quality Assurance Requirements

1. All supplier products must conform to the Global Funds Quality Assurance Policy as defined at: <http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/> Meaning that for ARVs, the products should be either WHO Prequalified by WHO or SRA approved.
2. As supplier products will be pre-qualified by WHO or approved by a Stringent Drug Regulatory Authority (SDRA), the 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) approved products (e manufacturing site, s APIs source, manufacturing process, specifications, packaging material), WHO or SRA Good Manufacturing Process (GMP) Requirements (as the case may be) and requirements relating to quality, safety and efficacy of the relevant supplier product.
3. Pharmacopoeia. 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 SDRA.
4. Shelf Life. 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 Supplier and the Buyer and as specified in the relevant Purchase Order. The supplier 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.
5. Completion of the certificate of conformance will be a representation and warranty by the bidder / potential supplier that they comply with each of the provisions of this subsection.

6. Legal Matters

By submitting a bid for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the Bidder agrees to the following:

1. 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 this Section. Other than the provisions of this Section, the only legal arrangement between the Global Fund and the Bidder will be through a definitive negotiated agreement after proposal evaluation and panel selection.
2. The Global Fund expressly reserves the right to amend, withdraw, or cancel this RFP process and/or its sourcing strategy, and to reject any or all bids, at any time and for any reason, without liability or penalty to any party.

3. Bidders shall be responsible for and bear their own costs, expenses, and liabilities arising in connection with the preparation and submission of a response to this RFP, as updated, amended or modified from time to time, and their involvement in the RFP process. In no circumstances whatsoever will the Global Fund be liable for any such costs incurred by Bidders, whether direct or indirect, irrespective of the outcome of the procurement process, nor if the procurement process is cancelled, altered or postponed for any reason.
4. There are no other arrangements or understandings between the Global Fund and any Bidder with respect to this RFP other than the text contained herein.
5. Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process or any other matter relating to procurement of ARVs (including investigatory findings) with Global Fund resources, including grant funds, 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 three, the place of arbitration shall be Geneva, Switzerland, and the language used at the arbitration shall be English.
6. 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 will apply to: (i) this RFP; and (ii) any other matter relating to procurement of ARVs with Global Fund resources; and these processes may include, without limitation, public disclosure at the Global Fund's full discretion of any findings and/or decisions.
7. 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 ARVs with Global Fund resources, 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 will not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of ARVs with Global Fund resources, 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.
8. Nothing contained in this RFP may be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund.

REQUEST FOR PROPOSAL
RFP No. TGF-14-040
ANTIRETROVIRAL Medicines

Schedule A: Officer’s Certificate of Conformance and Acknowledgement

*Proposing Suppliers are required to complete this Certificate as part of their proposal, and to return a version of this Certificate in PDF format as part of their proposal submission **signed** by an Officer of their organization with the ability to obligate the organization, including by signing a Framework Agreement with the Global Fund pursuant to this RFP.*

As a duly authorized Officer of the organization listed below, I confirm, acknowledge, and agree, on behalf of that organization, that:

1. The products and API Sources (s) offered in this RFP is / are prequalified by WHO and/or a Stringent Drug Regulatory Authority (state) as defined in Schedule B1 Section 2a. (Bidder to provide as annex)
.....
2. That there is no objection to the Global Fund validating the information with WHO and/or the Stringent Regulatory Authority designated in 1 above
3. To my knowledge, there are no contractual or legal issues preventing the organization from: (i) submitting this proposal; or (ii) supplying Antiretroviral Medicines (ARVs) per the terms submitted in this proposal at a future date.
4. I have read and understand, and the organization will comply with: (i) the Global Fund’s *Code of Conduct for Suppliers*, and (ii) to the terms contained in the RFP, including Section 6: Legal Matters. No conflict of interest exists or would arise in connection with the organization: (i) submitting this proposal; or (ii) becoming a panel supplier under this RFP.
5. If the organization is selected by the Global Fund as a panel supplier, it will be required to enter into a Framework Agreement with the Global Fund in order to supply ARVs per this RFP. That Framework Agreement will be based on one of the Forms of Framework Agreement included in the RFP documentation presented on the Global Fund’s website. The organization agrees to enter into such an agreement, other than any exceptions to that document as presented in a marked/track changes version of the Proposed Form of Framework Agreement submitted by the organization as part of its proposal submission, and agrees that any material modifications to the Form of Framework Agreement in that marked/track changes version may lead the Global Fund to decline to enter into an agreement with the organization.
6. The organization is financially sound and is not subject to any activity, either initiated by itself or by any other organization, that may materially affect its ability to supply the products included in its proposal submission, including, but not limited to, a change of ownership.
7. The products proposed in the enclosed proposal submission have been priced according to the technical and packaging specifications as defined in the RFP document and accompanying templates.

[Note: If your organization has any reservations, clarifications, or other descriptive information in connection with this Certificate, you may provide that information in the box below, or, as necessary, on additional pages, and submit that supplemental information as part of the signed version of this Certificate. Please note that non-compliance with any of the

provisions of this Certificate will be taken into account in the Global Fund's evaluation of your organization's bid submission.]

Signature of Official / Authorized Signatory

Name _____

Title _____

Date _____

Organization _____

**REQUEST FOR PROPOSAL
RFP No. TGF-14-040
ANTIRETROVIRAL MEDICINES**

**Schedule B: Response Templates
(Technical and Commercial, Request for Information and Development Road
Map)**

[These have been dispatched as separate Excel Files.]

**REQUEST FOR PROPOSAL
RFP No. TGF-14-040
ANTIRETROVIRAL MEDICINES**

**Schedule C: Forms of Framework Agreement between the Global Fund and
Panel Suppliers**

- 1. Supplier Partnership**
- 2. Supply Agreement**

*[To be provided separately on the Global Fund's website for this RFP
Current Scheduled Date for Issue is Wednesday 6th August 2014.]*

**REQUEST FOR PROPOSAL
RFP No. TGF 14-010
ANTIRETROVIRAL MEDICINES**

Schedule D: Form of Confidentiality Agreement

This Confidentiality Agreement (the “**Agreement**”) entered into as of.....(the “**Effective Date**”) is made by and between the Global Fund to Fight AIDS, Tuberculosis and Malaria, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland (the “**Global Fund**”) and.....
(Collectively the “**Parties**”).

The Parties intend to provide certain confidential information to each other in connection with a potential transaction relating to the supply of Antiretroviral Medicines, as further described in Global Fund Request for Proposal No. TGF-14-040 (the “**Purpose**”).

In this Agreement, the term “**Disclosing Party**” means the party that is providing Confidential Information, and the term “**Receiving Party**” means the party that is receiving Confidential Information.

In consideration of the Parties’ sharing of Confidential Information (as defined in Section 1 below), and as a condition to such disclosure, the Parties agree to the following terms and conditions as specified below which shall be effective from the Effective Date.

1. In this Agreement, the term “**Confidential Information**” means any information disclosed by a Disclosing Party to a Receiving Party, either directly or indirectly, which is not generally available to the public. The fact that such information has been delivered to the Receiving Party is also considered Confidential Information. Confidential Information includes not only written information, but also information transferred orally, visually, electronically or by any other means. Information will not be considered Confidential Information if the Receiving Party can prove that:
 - a. it already lawfully possesses the information,
 - b. the information is lawfully made available to the Receiving Party by a third party that is under no obligation of confidentiality to the Disclosing Party,
 - c. it developed the information independently, or
 - d. the information is, or becomes, publicly available other than as a result of any action of the Receiving Party.
2. The Parties shall keep Confidential Information secret and confidential and shall not disclose it to any person except, on a need-to-know basis, to a limited group of their own, and their affiliates’, directors, officers or employees, outside professional advisors, and auditors. Each party assures that each individual to whom Confidential Information is being disclosed or made accessible according to the stipulations above is contractually and/or legally bound to hold such information in strict confidence.

3. The Receiving Party may disclose Confidential Information where disclosure has been ordered to be made as a result of a subpoena or other binding request from any competent judicial, administrative, legislative, or regulatory authority or body. In such an event the Receiving Party shall as far as reasonably possible provide the Disclosing Party with prior notice without undue delay so that the Disclosing Party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement for the limited purpose of the required disclosure.
4. The Parties agree that, if the Purpose does not proceed or negotiations terminate for any reason, each will, unless otherwise requested by the other party or required by any applicable law, regulation, subpoena, or order from any competent judicial, administrative, legislative or regulatory authority or body, immediately return or, at the direction of the Disclosing Party, destroy all tangible documents and any copies and extracts made thereof and, to the extent feasible with reasonable effort, delete all electronically saved confidential information.
5. Nothing in this Agreement shall impose any obligation upon the Parties to enter into any negotiations or further agreement or to cooperate exclusively with respect to the Purpose.
6. The Parties acknowledge that this Agreement sets out the entire agreement and understanding between them in relation to the subject matter hereof and that it supersedes all previous agreements, arrangements and understandings between the Parties with regard hereto.
7. This Agreement covers all Confidential Information being exchanged on and after its Effective Date in connection with the Purpose and shall remain in effect for a period of three years from this day on irrespective of entering into any agreement in connection with the Purpose or its termination.
8. Nothing in this Agreement will create a relationship of partnership, agency, or joint venture between the Parties. Neither Party is authorized to act, or make any statement, representation, or warranty on behalf of the other Party.
9. Nothing contained in this Agreement will be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund under (i) international law, including international customary law, any international conventions, treaties or agreements, (ii) any national laws including but not limited to the United States of America's International Organizations Immunities Act (22 United States Code 288), or (iii) under the Headquarters Agreement between the Global Fund and the Swiss Federal Council dated 13 December 2004.
- 10.

[Signatures Follow.]



IN WITNESS WHEREOF, each of the Parties hereto has caused this Confidentiality Agreement to be duly executed and delivered by a duly authorized officer as of the Effective Date.

By: _____

Name: _____

Title: _____

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

By: _____

Name: _____

Title: _____

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