Issue Date: 15th August 2014

Subject: REQUEST FOR PROPOSAL (RFP) TGF 014-040

Round 1: Questions and Responses

Note where questions included a company name these have been modified to protect anonymity.

No	Question	Response
1	The forecast provided for Lpv/r 200/50mg Tablets for 2016 is designated as “anticipate level demand” Historically; the demand for Optimum 2nd Line PI/r has always presented growth. Kindly elaborate the “levelling”. Please clarify if the volumes listed in Schedule F are for 2015 only, or are they a combined total for 2015 and 2016? Specifically, is it 2,000,000 units of LPV/r 200/50mg for 2015 only or 2,000,000 units for 2015 and 2016 combined?	The figures presented are for a 12 month period so it indicates volume for 2015 and the same volume for 2016. Whilst we know that there will be overall growth in demand for ARVs in 2016 compared to 2015, it is more challenging to estimate the precise volumes for 2016 and hence in most cases we have made a conservative volume estimate for 2016. Additionally there are also other products for protease inhibitors. Kindly see separate notice on forecast revisions.
2	There is a likely split of award volumes beyond the 20% reserve for new entrants? How many suppliers are foreseen (e.g. for LPV/r 200/50 as "mature" category product)? What would be the likely % split awarded to each of the primary / secondary / tertiary suppliers	Precise numbers of vendors to supply each product will be finalized during the evaluation process. Our aim is to ensure both affordability and supply chain integrity and we will make our decisions on a case-by-case basis.
3	We have a corporate policy of not disclosing specific cost details of our products, given that we manufacture our own API as fully-integrated manufacturer and do not source externally? Specifically, unlike all other items listed there-in, page 16 of the RFP does NOT mark Product Cost as "evaluated" under "use by evaluation team", but rather as "for information" only, and only as potential input for road map development under a Supplier Partnership. We	Bidders need to consider the potential consequence of not fully responding to the RFP including providing the detailed information / data expected as is described in Section 3.4 of the Request for Proposal (RFP). Bidders also need to note Section 3.6.2 of the Request for Proposal, which provides as follows, among others, “[A]ny 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

No	Question	Response
	would be seeking a 2 year Framework Agreement only and thus the "road map" would be irrelevant.	that element is required for information only." This type of information could also be key in any subsequent review of pricing as described in Section 2.8 of the RFP. We understand you wish to pursue a two year Supply Agreement and the instructions for enabling this route are contained within the RFP.
4	Kindly confirm that a Schedule B3 ("Development Road Map") is only required if the proposed commercial approach is a 3+2 year Supplier Partnership?	Confirmed: Schedule B3 is only required for those bidders who wish to pursue a Supplier Partnership.
5	File : Solicitation TGF – 014-40 Schedule B1 1. In excel sheet 2a, 2b & 2c Packaging is mentioned; please confirm whether we need to provide the configuration, as pack size is already mentioned. 2. For the products which are under development/R&D stage which are already included in database, do we need to include this product in sheet 2c or in Excel File Schedule B3 (Development Road Map)	In this section we are specifically interested in the packaging type e.g. bottle, co-blister etc. If you have products, which are currently undergoing pre-qualification or other SRA approval, you should provide the requested details against that specific product. It is your choice whether you include this in Schedule B3. However be advised that the development road map has broader goals than purely new product introduction and the specific objectives are detailed in Section 3.5 of the RFP.
6	File : Solicitation TGF – 014-40 Schedule B2 In Sheet 3, Customer History, they have asked to provide names of Top 3 customers to which we are catering along with volumes. Is this required for entire products or for ARV products only? In sheet 5, Lead Times – In column Lead time till First Production completes. Does it mean the lead time for Batch or entire Order qty. If order qty, it will then be	This is required for ARV products only. This is intended to mean lead-time until the first production batch is completed.

No	Question	Response
	dependent on order qty.	
7	In case of API manufacturing delays or failure which are out of our control, how will Global Fund support us in such issues.	Manufacturers are expected to assure API supply security and this will be evaluated – however the Global Fund will assess each case on the individual circumstances prevailing. It is our intention to assist our supplier wherever possible; however, our main priority must be to ensure continuity of supply to those who need treatment.
8	If multiple products are awarded in a tender, do we have choice to supply particular products.	No, the Global Fund will assume that if you bid a product you are willing to supply that product and when multiple products are awarded to a supplier, it is expected that the Supplier will supply all the products on the award. The Global Fund will allocate volumes to successful bidders using the criteria defined in the tender document.
9	If price variation occurs in RM/PM, how it will addressed.	We have assumed RM/PM means raw materials and packaging. The tender contains an opportunity for you to propose price protection mechanisms and the Framework Agreement Section 4 explains the price review process.
10	In case of Bulk packs, can we supply them without cartons.	All packaging must comply with the packaging specifications defined in the tender document. If however you believe there is an opportunity to reduce cost by omitting the carton the tender also provides the chance for you to express this opportunity in Schedule B3.
11	Devaluation of Indian rupee in cases where the input material is imported and how the same will be addressed.	We assume that question 9 and 11 are addressing the same subject. The RFP contains a section in tab 8 of Schedule B1 for bidders to submit their own proposals for price protection mechanisms, so that these may be evaluated by the Global Fund.
12	At Page 3 of the document "Solicitation_TGF-014-040_RFP_en" (hereinafter referred to as "Doc. STR"), there are two types as "Supplier Partnerships" and " Supply Agreements". However, we are still not very clear	1. The difference between the two types of relationship can be further understood if one examines the two different types of Framework Agreements specifically Sections 5, 6, 8 and 15 of such Framework Agreements. The Framework Agreements were

No	Question	Response
	about the difference between them. Which kind of bidder can be determined as Type 1 and which can be Type 2?	posted on 6th August. 2. The Type 1 and Type 2 classification refers to the type of Framework Agreement and not the bidder. Allocation of Framework Agreement types will be undertaken subject to the criteria explained in Section 2.2 of the RFP and the evaluation criteria defined in Section 3.6.6 of the RFP.
13	At Page 3 of Doc. STR, we are confused about the "PPM countries". Could you please provide the definition of PPM countries?	PPM refers to the Pooled Procurement Mechanism, which was previously called "Voluntary Pooled Procurement" VPP. This is a structure whereby the procurement of core health products is conducted through the Global Fund contracted Procurement Services Agent. The countries that are currently using the PPM are listed in Schedule B2 under the 'National Registration' and 'Licensing' tabs.
14	In the first part of section 1.3 of Doc. STR, the product should be in compliance with the Global Fund Quality Assurance Policy on Pharmaceuticals. Our product do not have the FDA GMP (FDA do not give GMP certificate to products but manufacturer) whereas our factory did have FDA GMP. Can such kind of product be accepted?	We only procure products that are approved by Stringent Regulatory Authorities or prequalified by WHO PQ at the approved production sites in accordance with our Quality Assurance Policy as indicated in the RFP.
15	At point 5 of section 1.3, does "bid security" means the none-purchase for the submit?	No. Some tenders require a financial guarantee that the bidder will be able to undertake the activities as proposed in their submissions. This tender does not include that requirement.
16	At point 1 of section 2.8 pricing, does "all pricing will be on an open book basis" mean that our price can be seen by others? We feel a little bit confused.	Open book pricing refers to the fact that in your submission the Global Fund requests you provide a breakdown of your pricing as defined in the Schedules. At the time of tender all your pricing will remain confidential between you and the Global Fund and we are prepared to sign a confidentiality agreement to cover that undertaking. Thereafter

No	Question	Response
		access to different tiers of pricing is indicated in the Framework Agreements.
17	At point 3 of section 3.3 of Doc. STR, Schedule C is mentioned. But we have not found the form of framework through the internet till today. Is it update in the website? When should we submit Schedule C? At Stage 1?	The Type 1 and Type 2 Framework Agreements were posted on our website on Wednesday 6th of August and you are requested to submit marked up copies with your Stage 1 submission.
18	At point 7 of section 3.4, Schedule J is mentioned. Could you please help me to find Schedule J? Is it a missing enclosed document?	Schedule J was originally attached to facilitate workshop planning. However we have decided to publish the planned week of the workshops and then conduct detailed planning with individual bidders following the stage 1 evaluation.
19	The last inquiry, do we need to send samples during the bid TGF-014-040?	No. All products that you bid must conform to the specified quality and pre-qualification requirements defined in the tender.
20	Under Section 2.5 of Global Fund RFP, "Contracting", we would like to have clarification on the criteria for selecting supplier for Supplier Partnership or Supply agreement. Weighting for prices, lead time, API integration, shelf life etc.	Regarding the criteria we would refer you to the answer to question 12. The Global Fund will not be advising bidders of the detailed weighting of the individual criteria except at the level defined in the RFP.
21	Under section 2.7 "Contract management", we would like to know if vendors offering prices to Global Fund through this RFP will also be obliged to supply to PFSCM (for PEPFAR project) and other procurers like UNICEF,PAHO,UNDP etc on the same prices as Global Fund RFP since PFSCM will do procurement & will perform operational management on behalf of Global Fund.	There is no obligation under this tender for any bidder to supply products to other procuring agencies or channels at the same price as submitted to the Global Fund. However the Framework Agreements do permit the sharing of pricing on a tiered basis with others, subject to the agreement of both parties. At present no other agencies have requested this facility for ARV products [note: the templates for the Framework Agreements are posted at http://www.theglobalfund.org/en/procurement/]
22	Under section 2.8 of "Open Book" prices we will not be	We acknowledge that Section 2.8 requests significant detail and

No	Question	Response
	comfortable sharing breakdown of API prices, supply price & cost etc. We can share API rates per kgs.	we are prepared to sign a confidentiality agreement with you to protect that information. Bidders need to consider the potential consequence of not fully responding to the RFP, including the detailed information / data required as is described in Section 3.4 of the RFP. This type of information could also be key in any subsequent review of pricing as described in Section 2.8
23	Under section 6 "Legal Matters" bullet 2, we would like to have clarity what are the possible circumstance under which Global Fund can consider withdrawing or cancelling this RFP. We would also like to know if the clause can be applied vice versa whereby suppliers can withdraw the bid. In this scenario whole purpose of this exercise will be futile if the RFP can be cancelled under any conditions which are not stated.	This clause is a standard clause included in all Global Fund tenders to protect the Global Fund in the event of unforeseen events. This is also a standard provision in all public tenders, recognized as an international practice by public agencies (commonly referred to as a "reservation clause"). This tender has been prepared in good faith and following a great deal of work and at the time of writing there is no intention of cancelling it. Bidders may decide to withdraw their submissions, but this risk will be factored into our evaluation.
24	We would like to know if Global Fund will compensate a vendor in situation where the Purchase orders are not placed by Global Fund as per committed allocated volumes as the prices are going to be quoted accordingly.	It is the intention of the Global Fund to place orders in line with the committed volumes. How the committed volumes are managed is shown in the Sections 5 and6 of the Framework Agreements.
25	We would like to know % weighting given to the below parameters while evaluating the bid: Offered Price. Shelf Life. Backward API integration. Past Performance. Existing capacities.	The Global Fund will not be providing evaluation criteria other than those provided in the RFP.

No	Question	Response
	Registration. WHO Approved ARV (A), USFDA approved ARV (B) or both (A & B). Others (if any).	
26	We would also like to know if there are any monetary penalties that will be imposed on vendors, if so, under what possible scenario(s) the penalty will be imposed. As ARV's are low margins we would like to know the same.	The Global Fund expects suppliers to meet their obligations and we refer you to the RFP and Framework Agreement documents concerning our approach to managing supplier performance
27	We would like to know if agreed pricing with Global Fund will be made public and will be informed to other global procurers as well and on GF site as well.	We would refer you to the answer to question Q21. All Global Fund procurement transactions are eventually reported under Price and Quality Reporting (PQR) system. We will, if required, explore how this process could be modified.
28	We would like to know timeline to apply for price increase/escalations, frequency & procedure for the same as there are some scenarios wherein impact comes much sooner due to Forex rates, API rates, country scenarios etc.	The Global Fund has asked bidders to present their proposals for price protection in tab 8 of Schedule B1.
29	We would like to know the payment terms with Global Fund once a vendor is chosen for supply of ARVs. We would also like to know if vendors will be compensated incase payments are delayed beyond stipulated payment terms or pick up of countries are delayed.	Standard payment terms are 30 days from receipt of invoice under the terms of the PSA Terms and Conditions. We will be issuing a notice to correct the stated (45) in numerals to (30) in numerals in (refer to Section 5.6.d of the Framework Agreement) Compensation mechanisms do not currently exist and as part of the framework contract negotiations, we expect some level of flexibility but this can be further discussed to ensure these issues are kept to a minimal level. We also refer you to point 6a of Section 3.5 of the RFP.
30	We would also like to know if there are any provisions for	The terms of payment as articulated on the PSA Terms and

No	Question	Response
	advance payment to vendors in-case goods are ready as per requested Inco date but have not been picked from manufacturer's warehouse. We would also like to know if Global Fund will support vendors with storage charges in such a scenario. We can inform such charges per CBM.	Conditions are linked to when the supplier has fulfilled all their obligations under this Incoterm and agreed delivery / pick-up schedules. Whilst we do expect some level of flexibility, this can be further discussed as part of the ongoing efforts to minimize the challenges in deliveries For any advance payment – suppliers are required to submit proposal in response to the RFP.
31	We would also like to know how many vendors per product will be considered while evaluation & also while awarding a particular ARV & criteria if any for deciding the maximum number of vendors per product.	The number of vendors for each product will be determined as part of the evaluation and allocation process based on the evaluated criteria and the available manufacturing capacity of successful bidders.
32	Volumes based pricing & retrospective in case those volumes are not covered.	We have interpreted this question to mean what is the impact on volume discounted pricing if that volume is not met. Our evaluation and allocation process takes into account the volume-discounted price at the volume committed. This is to avoid the scenario suggested. If for any reason that volume was not met then products would be re-priced at a lesser discount.
33	MFN clause: same quality & other parameters e.g. if countries don't procure the same quality prices can be different.	The MFN clause relates to products of the same specification and quality.
34	A number of ARV products have been developed by our company & are under filing/approval status with WHO and/or USFDA. We would like to know if we can submit our bid for these products	No. We can only accept bids for products that are currently pre-qualified or approved. However our strategy has been specifically designed to ensure that newly qualified products are offered the opportunity to be included. This is why in most segments a percentage has been left open for new entrants as described in Section 2.6 of the RFP. For the products you have in your production pipeline, please complete tab 2c in Schedule B1 and then advise us when approval is complete.

No	Question	Response
35	Going through the RFP TGF -14- 040 for ARV, I noted that products like Darunavir and Etravirine are listed in schedule F under the adult 3rd line as well as Paediatric products considered of limited use by IATT It was my understanding from the discussion at the Global Fund – PEPFAR ARV manufacturers Engagement meeting in Dubai on Tuesday June 24th, that with respect to these products of low volume, Global Fund would initiate discussions in 2015 with respective manufacturers. I would therefore appreciate if Global Fund could confirm whether it expect the originator companies to respond to the RFP for these products that are considered emerging and for which there may not be any alternative available for the moment. I also would like to draw your attention on the fact that the pack size for Darunavir 300mg tablets is of 120 tablets (instead of 60) (see product database in Schedule F). Moreover, the production of the 300mg Darunavir formulation is being phased out and will be replaced by the 600 mg tablet formulation.	Thank you for the update on the product including correction of the pack size– for any discrepancies in the pack sizes, please include a comment on the applicable "notes" sections throughout. Whilst we have announced that we will be engaging with originators to further understand the future pipeline and opportunities and to simplify the supply of specialist low volume products in Q1 2015, no eligible supplier is precluded from participating in this RFP. We will continue to procure ARVs that cannot be supplied under the outcome of this RFP on an individual purchase order basis.
36	If a single product has multiple sources of API & multiple formulation Manufacturing facilities a. Can we include these multiple sources data in the same row	This is fine as long as it is clear and it is the product and the sites that are approved accordingly by the relevant SRA as indicated on our Quality Assurance Policy.
37	If a manufacturer has an alternative pack size/alternative product description – can we amend the pack size in the prescribed format or else do we need to mention it in	If you have an alternative pack size to the ones offered please add these details in the additional notes section.

No	Question	Response
	additional notes given below in the specified sheets(Ref 2.6)	
38	Schedule B-2. Can we just give number of packs we can offer per month by Product to Global Fund. Instead of available & total installed capacity in number of packs. How do we highlight, as product wise capacity is varying. Also, a particular product may be manufactured in more than one plant, so do we give plant-wise or product-wise. Or as suggested in template we give basis product categories with similar capacity products being clubbed together. Please give more clarity on how capacities to be defined & understood by product. And what is granular analysis. Installed Capacity, are we asking for ARV's only & to be given in packs.	Our key objective is to understand the number of packs you are able to provide a month by product. If it is simpler for you to group products together and answer in a different format that is fine. The template has been designed to understand the impact of substituting one product for another but if it is not required and you can provide the information in a more simple fashion that can be readily understood that will be fine. In this context granularity as defined in the instructions to the relevant tab means more detailed analysis.
39	Please give clarity on Lead Times. What is the difference between the first lead time & subsequent lead time for 1 month PPM demand. For e.g. For the first supply we will give a lead time say 8-10 weeks, thereafter for the next month supply it will be as per forecast given by product in terms of capacity per month. But we need to have clear visibility & firm orders for the whole year.	'Lead time till First Production Completes' means the first batch has completed the packaging stage. ' Lead time for 1 month PPM demand' means the lead-time to complete the production of 1 month's worth of the annual PPM demand for that product.
40	Schedule J. Can you please share. Seemed to have missed it.	Our mistake, please refer to the answer to question 18.
41	Please confirm Basic advantages & disadvantages of Type-1 & Type 2 Agreement.	The advantages and disadvantages of the different types of framework agreement are dependent on the objectives of different bidders.
42	In Type-1 Does it allow price revision after 1 year. What about Forex.	We shall answer Q42, 43, and 44 together. 1. The times and the conditions under which the pricing may be amended are detailed in Section 4 of the Type 1 Framework Agreement.

No	Question	Response
		2. A Price Risk Management is an approach to managing price fluctuation on a basis of shared risk and specifically includes foreign exchange risk. 3. Bidders are requested to submit their own proposals for managing price risk in Schedule B1, so that these may be evaluated by the Global Fund..
43	Price Risk Management, What is this, as mentioned in B-1.	See above.
44	Price Adjustment Mechanism- What would be the time frame. We should have a common framework for this for all suppliers.	Please read Section 4 of the Framework Agreements.
45	Foreign Currency- What Exchange Rate to be taken. Will this be at constant Exchange Rate for Long Term contracts.	We propose bidders to present price risk management proposals for exchange rate risks as described in Section 2.8 and schedule B1, so that these may be evaluated by the Global Fund.
46	Force Majeure condition, such as, as seen in case of Zido API supplies & prices. How do we handle similar situation, where this would impact prices & supplies.	It is impossible to be specific for every eventuality. We would refer you to the answer to question 7.
47	Can we have + 5 % change allowed in Delivered Qty in case of specific packs.	No. Our funding arrangements will not support continuous over delivery.
48	Can we have a mechanism by which forex change of more than say +5% allow us to revisit the price & accordingly price benefit allowed. Will give us flexibility to be more aggressive. B-3 Template is slightly tricky to understand. Can this be elaborated. Such as point number 5 on Page 12 in the RFP. Will this be governed by specific agreements. Is Global Fund willing to allocate resources & funding to it.	Please refer to the answers to questions 42,43 44 and 45. Suppliers do have an option to choose whether to have a collaborative project or not. However, it is the intention to enter into a series of collaborative projects with selected vendors to create value as defined in para 6 of Section 3.5 of the RFP. Where appropriate it is also the intention to share this value between parties. To ease the administrative burden the projects will not be covered by specific agreements and the Global Fund will

No	Question	Response
		ensure that, from its side, sufficient resources and funding (subject to the caution expressed in the General Instructions, Page 1 Background) are available to underwrite its responsibilities for delivery.
49	Can you please elaborate more on the point number 9, page 13 in RFP. Can we include potential pipeline products which are under development into this.	While you may include new pipeline products in Schedule B3 they will not be considered unless you are able to demonstrate that their introduction will create clear measurable value. We have also offered you the facility to identify the products you have in the pipeline in Schedule B2 tab 2c. If your pipeline products are yet to enter a pre-qualification or SRA approval phase please feel free to add them in the additional comments.
50	For B-3 can Global Fund & WHO identify key tasks which will be in line with treatment goals And suppliers pitching for those tasks & partnerships.	Some specific objectives are specified in Section 3.5. It is the intention of the Global Fund to work more closely with partner agencies including WHO to identify the development path more clearly. This work has not yet commenced and it is unlikely to result in specific suppliers being allocated specific activities.
51	We are in the process of a merger, which is likely to significantly improve our supply capability or our capability to have our own API & make significant cost reductions in the same. Will this RFP allow us an opportunity for Global Fund to review our score & capabilities next year.	You should base your tender on the position today. Future improvements to the supply chain and potential price reductions for future years can be offered either in the discount section or as an objective in Schedule B3. In both case we would advise that the potential benefits should be quantified. Any merger should also ensure that the Global Fund will be contractually engaged with the same principal in a consistent manner.
52	Can we participate for those products being contract manufactured say within India or Outside India. Some of the products/Manufacturing locations are in the process of WHO approval. Is the price fixed for 3 years or are there annual pricing	You may offer products from any manufacturing facility with which you have a commercial arrangement subject to them meeting all the requirements specified in the tender. However you must specify these locations individually. If the location is currently undergoing WHO approval please enter the details in Schedule B1 tab 2c. Please refer to the answers to questions 42, 43 and 44 and

No	Question	Response
	discussions? If it is fixed, are there allowances for currency fluctuations or changes in operating costs?	Section 4 of the Framework Agreements.
53	Open book pricing – would the API prices be made public at anytime either during or after the tender?	It is not our intention to reveal API pricing to any party either during or after the tender. We are willing to enter into a confidentiality agreement with you to cover this fact.
54	Is it acceptable to quote for one pack (general export pack in English) for all countries?	While you may quote for one standard export pack, you may be unable to supply to all countries, which have their own specific packaging requirements.
55	Any further information as to how the estimated annual volume would be split between chosen suppliers? If yes how many suppliers and is there specific % split?	We would refer you to the answer to Question 31.
56	When is the expected 1st supply required? (E.g. Q2 2015?)	We anticipate first purchase orders being placed from Q4 2014 for delivery potentially from late Q1 2015.
57	What will be the purchase phasing? One delivery per year or smooth/ regular supply over the year?	It is our intention to optimize delivery in line with available capacity so that manufacturers can maximize the return on their assets and the Global Fund can meet its commitments to its recipients. As a default for large volume products we would look to regular supply through the year but for smaller volumes we would seek to optimize the schedule for both parties. If you have specific issues in this area we would request that you highlight them in the appropriate additional notes section.
58	Do we need to confirm the same regulatory status over the total timeframe of the tender? For example there it is possible that there could be some site changes during this time.	In awarding a Framework Agreement we would anticipate that, at a company level, the same regulatory status will be maintained. If within this there are certain site changes we will accept this subject to the new site having all the required approvals, registrations and licenses and your notification to us of any forthcoming change.
59	Could we see a draft of the terms of the type 1 or type 2 framework agreements that are being referred to under 2.8 Pricing of the RFP document?	Type 1 and 2 Framework Agreements were published on Wednesday 6th August.
60	As the price is ex-works can we get confirmation that the	Please refer to Schedule F (the PSA Terms and Conditions),

No	Question	Response
	products will be picked up from the manufacturing site? In schedule B2 “company details”. Do the 1.2. Manufacturing locations refer to the final packaging/release site or the formulation site?	attached to both types of the Framework Agreement. These details relate to the packaging release site. Additional information regarding formulation is requested in a different section.
61	In schedule B2 “customer history”. We are the originator and supplier of the products we are quoting for in the US and in Europe. Do you require us to fill in this section?	We would ask that you complete as much as you can.
62	Do we understand correctly that schedule B3, development objectives is for ideas to improve either cost or processes only?	While both cost and process can create value there is actually no limit to the objectives that can be included as long as they meet the criteria shown in Section 3.5 of the RFP.
63	How will the extension period be managed? Will suppliers automatically awarded an extension or will it be an open tender process?	The extension will be automatically awarded subject to the partner meeting the criteria defined in the Framework Agreement. If they are unable to meet these criteria the Global Fund will either allocate their volumes to other parties or issue a tender.