TGF-18-010 Global Fund Response to Requests for Clarification

20 February 2018

	Question	Response
1.	As a new company joining the procurement market for the first time, even after sharing the list of countries to which we are planning to enter, there may be some changes to the regulatory strategy. In that sense, we would like to once again confirm that the changes to RFP with acceptable justifications can be made after it going into effect.	See section 3/F/10/1b: Country Coverage: bidders should only submit information in Schedule E1 if they have formally received confirmation of registration/ authorization for use in the country. Inclusion of products with anticipated country registrations/ approvals will result in exclusion from evaluation of this element. In case of award, suppliers will be responsible for keeping this information up-to date to support contract implementation as is described in the Framework Agreements (Schedule C1 & C2). Note the description of allocation in subsequent periods in Section 5.3 of Schedule C1: Supplier Partnership Framework Agreement.
2.	Can we submit our country registration plans for strategic products in case filings are not complete so far for few of the new products?	
3.	Do we need to submit registration certificates of in-country registration?	No. Submission of registration certificates is not required by the RFP closure; however, the Global Fund may validate any information submitted at any time during or after evaluation.
4.	Page 14: Clause 12.6: We intend to describe the total number of registrations. Is this sufficient or you want us to break it down in each country?	"Participation on WHO Collaborative Procedure for Accelerated Registration and sub-regional Registration initiatives": This is information for implementation. Please provide the necessary detail for us to understand the associated number of products and national registrations obtained as a result of participation in the WHO Collaborative Procedure and sub-regional registration initiatives.

5.	Do we need to submit signed and stamped • Schedule E to Schedule C (TGF 18 010_PAHO Terms and Conditions) to express our acceptance against Global Fund's terms and conditions? • Section 5 Legal Matters (page number 23 of tender document file) • Selected Framework Agreement (C1 or C2)	No. Bidders must complete Schedule A: Officer's Certificate of Conformance and Acknowledgement that includes acceptance of a number of elements including these (PAHO Terms and Conditions are Schedule E to Schedule C1 of the RFP: draft Strategic Partnership Agreement). Any reservations, clarifications or amendment requests must be outlined in the signed and completed Schedule A at the time of submission of the proposal.
6.	Considering that Global fund is ready to review reservation or request for amendment in the Strategic Partnership Agreement & Purchase Order Agreement, please do let us know the process to highlight if we have any reservation or request for amendment on the same.	Limited and non-material changes to the Framework Agreement may be considered by the Global Fund. Any reservations, clarifications or amendment requests must be outlined in the signed and completed Schedule A at the time of submission of the proposal
7.	We have comments on certain aspects of the Framework Agreement including supplier conduct and dispute resolution	
8.	We would like to have Schedule B Form of Confidentiality Agreement from TGF. To whom we should ask for that?	Please print, sign, and send Schedule B back to the Global Fund using the iSupplier online discussion platform. We will provide the required signatures and send back to you.
9.	As per our understanding, we must submit below mentioned files. Please confirm if any other documents are missing. a. Schedule A - Officer's Certificate of Conformance and Acknowledgement b. Schedule B - Form of Confidentiality Agreement c. E1: Technical (in excel and signed PDF version) d. E2: Commercial (in excel and signed PDF version) e. E3: For Information and Implementation (in excel and signed PDF version)	The required documents and format for submission are indicated in Section 3 of the RFP: Instructions to Bidders • D: Preparation of Proposal • E: Submission of Proposal
10.	What kind of supporting documents do you need for the tender, in general/overall? Can we have a check list of documents?	
11.	Strategic partnership lifecycle term is for 2018 or for complete 3.5 years i.e., 2021	The term of both types of Framework Agreements is up to 31 December 2021 (Section 4 and Schedules C1 and C2 of the RFP)
12.	Projects to deliver on strategic objectives – additional details should be provided separately. Please advise if we can submit additional data in	The additional detail can be submitted in either Word, Excel, PowerPoint or PDF formats.

	word document or PPT? And provision to upload this document on the portal will be available?	
13.	Can we have one more round to submit clarification questions to the RFP before the close of the RFP/16 March? Or may we ask questions for clarification on an ongoing basis until the close of the RFP?	We will open a second (final) opportunity for clarifications • Deadline for prospective bidders to submit clarification questions: Thursday 1 March: 17:00 Geneva time • Latest date for the Global Fund to issue responses to clarification questions to all prospective bidders: Tuesday 6 March
14.	In the Technical and Commercial evaluation, what is weightage given for each parameter?	Please refer to Section 3 "Instructions to Bidders", Paragraph F "Evaluation of the Proposal" in the RFP document.
15.	If we chose the strategic partnership agreement and are not successful in getting an award under that agreement will we be automatically considered for the purchase order agreement.	Based on the results of the evaluation, the Global Fund may offer a PO Agreement. However, if a bidder has selected the option of the Purchase Order Agreement, in case of non-award, the option of the Strategic Partnership Agreement shall not be available.
16.	Can we select for strategic partnership agreement for few products and purchase order agreement for other products OR do we have to stick on only one agreement for all the products.	No. Bidders should make there submission selecting only type of agreement in Schedule E1-E3.
17.	Can a company participate in both Framework Agreement models?	
18.	As an originator, we are engaged to supply when a generic version of our formulation cannot or is not available to be supplied to a country - please advise if this RFP applies to us.	Part of the intent of the Purchase Order Framework Agreements is to bring the procurement of all of the ARV needs for the Pooled Procurement Mechanism under the direct management of the Global Fund (vs through our procurement agent) including, but not limited to, originator companies in the circumstances described.
19.	As an originator, we have different pricing for some countries, how do we enter that into Schedule E1	Please use the comments section located to the right of each question to articulate any additional information that cannot be entered into the main response section.

20.	In the RFP (Technical), it is mentioned that "Please identify products that you offer from the list below. For related products used in HIV program set a product from the dropdown list and indicate pack size offered. If a product is strategic and not yet approved, please indicate anticipated QA approval date in 2018" Are we only allowed to include the information on the products which are already submitted and expected to be approved in 2018? Since we have a series of products to be submitted and approved within 2018~2021 period, your answer will help us write in the right direction.	Information on products that are expected to be approved after 1 January 2019 should not be entered in Schedule E1. Rather they should be submitted in Schedule E3: "Pipeline products".
21.	We currently don't have ARV products which are WHO prequalified / USFDA approved but have planning to file a few ARV products by the end of 2018 for WHO prequalification / USFDA approval. Please do let us know if we can participate for the products which we intend to file for WHO prequalification. Please do let us know the forms which we need to fill for pipeline products which we expect to file for WHO prequalified / USFDA approved before Dec 2018. This is considering that there are a few forms which ask for details costing which we might not be able to provide till be commence commercial supply of those products. Others forms also ask for WHO approval number / SRA approval numbers which is currently not available with us.	
22.	Considering that TLD is a pipeline products for us, it will not be possible to fill details of Schedule E1_Techincal (E1.3c Supply security and visible) which requires specific detail of current stock, planned production output etc. Please suggest on the same.	
23.	Please clarify whether the "Anticipated QA approval date" as captured in the Schedule E1 Technical file refers to SRA/WHO approval date of the product, or related to any other reference?	This relates to Strategic Products and refers to anticipated compliance with the Global Fund's Quality Assurance Policy – see Section 3/F/10/1a (page 12)

24.	We have filed some products for SRA and/or WHO PQ approval. We expect approval in September 2018. We would be happy if we are allowed to quote. We can share proof of submission.	For certain products, the Global Fund may determine that a portion of the available volumes will be reserved for newly eligible products (from new or existing suppliers) that become compliant with the Global Fund Quality Assurance Policy after the close of the RFP. See Sections 4/B/4a/vii (page 17) and Section 4/D/9 (page 20), Information on products that are expected to be approved after 1 January 2019 should not be entered in Schedule E1. Rather they should be submitted in Schedule E3: "Pipeline products".
25.	Page 12, clause 10.1.a: Does this mean product submitted for SRA / WHO PQ / ERP evaluation before 16 March, 2018 will only be eligible for next 3.5 years of LTA period?	
26.	Page 12, clause 10.1.a: As per this point a conditional allocation will be given to products which are already submitted for WHO PQ / SRA / ERP evaluation; will this condition expire after elapse of certain months into the LTA period?	The conditional allocation will be for the first allocation period and determined pro-rata for the remaining in that allocation period. The first allocation period as defined in the draft Framework Agreement will be the 3rd and 4th quarters of 2018. The principles of allocation and commitment are fully outlined in Section 5 of the draft Strategic Partnership Framework Agreement (Schedule C1 of RFP).
27.	Is there any EOI for ERP expected in 2018	This question is not directly related to the RFP; however, it is anticipated that there will be a regular full-scope ERP round launched in Q1 2018.
28.	Our Understanding is we can quote for TLD. We will be submitting the EOI for ERP review in Feb, 2018. We have also filed in WHO PQ. We have filed for certain packs but were not aware of a requirement for pack of 180, which we intend to quote & file additional pack.	Strategic Products including TLD are eligible for submission if they are compliant with the Global Fund's Quality Assurance Policy or for the purpose of evaluation, submitted and accepted for review by the WHO Prequalification Programme, a Stringent Drug Regulatory Authority or the Global Fund's Expert Review Committee – see Section 3/F/10/1a (page 12). Whilst most of the current demand is for the 30 pack of the 1st line regimens, WHO recommends dispensing for 3- and 6- month for stable patients which may translate into requirements for 90 and/or 180 packs. Information on products that are expected to be approved after 1 January 2019 should not be entered in Schedule E1. Rather they should be submitted in Schedule E3: "Pipeline products".
29.	For Products submitted for WHO PQ & not approved yet, do we need to submit proof of submission?	This is not compulsory, but would be helpful. The Global Fund may validate any information submitted at any time during or after evaluation.

30.	In our proposal, can we submit possibilities of adding new manufacturing sites which are closer to demand but yet not identified? If yes, then Schedule E, for these prospective sites will not be available for submission in our proposal. Will that be considered during evaluation?	Only approved manufacturing sites should be submitted in Schedule E1 for evaluation of the RFP submissions. However note the description of allocation in subsequent periods in Section 5.3 of Schedule C1: Supplier Partnership Framework Agreement. This could also be considered to be presented as a Project to deliver on Strategic Objectives (section 3/F/10/4 (page 13)
31.	Can we submit plans for adding new API sources?	Only approved manufacturing sites should be submitted in Schedule E1 for evaluation of the RFP submissions. However note the description of allocation in subsequent periods in Section 5.3 of Schedule C1: Supplier Partnership Framework Agreement.
32.	Please define "Strategic Products" as captured in Schedule D of the tender document; and advantages to the bidder in offering a strategic product compared to other products.	Strategic Products include both ARV (in Product Set 1) and non-ARV medicines (in Product Set 3) and have been determined by the Global Fund as important products in relation to its Procurement Strategy. For the ARVs, the list includes key products with limited availability where demand is anticipated to grow in the evolution of demand of alternative regimens from the current WHO guidelines. For the non-ARV medicines, one of the stated objectives of the Global Fund's Procurement Strategy for Antiretroviral and Other Selected Medicines used in HIV Programmes is to leverage its spend to improve access to selected strategic non-ARV medicines used in HIV programs (Section 4). This will be evaluated by assessing "Product Coverage" (Section 3/F/8) and could be presented as a "Project to deliver on Strategic Objectives" if proposed by a bidder
33.	Can you confirm the requested quantities of the Hepatitis C products listed?	Product Set 3: Non-ARV medicines used in HIV Programs: The selected medicines in Product Set 3 include those where access is limited and where the supply base and/or quality requirements has been assessed to be similar to that of ARVs. Different procurement strategies are expected to be developed for other products with different dynamics.
34.	Product Set-3: Other selected Medicines: A. Do we have any volumes or MOQ.	

35.	What will be the selection criteria for non ARV products which are mentioned in the RFP and will GF be procuring these products and indicative volumes? We would also like to know if Cotrimoxazole, Fluconazole and Acyclovir are not a part of Non ARV requirements as these products are widely used in opportunistic infections	At this time, the Global Fund does not yet have demand visibility for this product set. The focus for this product set is in the first instance to improve access to the products by listing them as available for procurement (including through "additional buyers" and simultaneously working with suppliers on improving affordability).
36.	Product Set-3: Other selected Medicines: B. Can we offer existing SRA approved packs. In terms of packaging /current packs. C. Some of these products may be registered/approved in a country, but the specification filed in emerging markets may not be the same as those of an SRA. Can we still supply these SRA approved packs. D. Alternative could be we have the art works developed & approved by the Global Fund QA team for the SRA approved packs. We can develop multi-language one type specific packs for supplies	Yes, providing the Stringent Drug Regulatory Authority (SRA) is within the definition included in the RFP. Products not approved, or not submitted and accepted for review to the WHO, SRA or ERP should not be submitted in Schedule E1. Rather they should be submitted in Schedule E3: "Pipeline products" (reference section 3/ F/10/1a).
37.	The Strategic product says "yes". Do we have to offer those products only, (or) are we eligible to offer the other products forming the list?	The "Yes" labelling identifies for convenience those products which are listed in Schedule D as "Strategic Products". Bidders can submit for any products listed in the RFP.
38.	There are some products which are recommended in PEPFAR priority list and may feature in WHO recommended list as well in end 2018/early 2019, can we offer those products as tender is scheduled till end 2021,is there a provision to add new products while the tender is ongoing.	The scope of the RFP is for bidders to submit proposals to supply "World Health Organisation recommended Antiretroviral Medicines" (Section 1 of RFP). Should WHO recommend new products then the Global Fund will incorporate these in implementation including managing existing allocations as described in section 5.7 of the draft Strategic Partnership Framework Agreement
39.	Current API Prices are very unstable because of the intermediate issues in China. Would there be any scope for reconciliation of prices if the situation becomes more adverse. Including any substantial changes in Exchange Rate (Forex).	Section 3 of the draft Strategic Partnership Framework Agreement (Schedule C1 of RFP) describes pricing including the price adjustment mechanism

40.	Total Landed Cost: Will there be separate RFQ's floated for supply on these terms. Current Prices quoted, Ex-Works. I hope this understanding is correct.	No. The Global Fund will determine the Total Landed Cost, based on historical freight cost data (Section 3/F/11/1 (page 13)
41.	For GS1 bar coding, up to what level (Primary, secondary or tertiary), kindly confirm if Global fund insisting on GS1 implementation for new comer in this bidding opportunity?	At this stage we are requesting information on where the bidder is with implementing GS1 or willingness to establish a barcodes tracking system in conformity with GS1 standards and the Global Fund's yet to be articulated implementation strategy that will be developed in consultation with suppliers. (Reference Schedule E3/question 3 and Section 4.2 of Schedule C1: draft Strategic Partnership Framework Agreement.)
42.	Can a non-related company be a participating company on behalf of a WHOPQ supplier?	No, the objective of the RFP is to select a panel of FPP manufacturers who will enter into Framework Agreements to directly supply WHO-recommended Antiretroviral and other selected medicines. (Section 4/B/1).
43.	Can you clarify how a new bidder without delivery history will be evaluated for OTIF?	The evaluation of such a bidder will not take OTIF into account, and bidders without historical OTIF will be neither advantaged nor disadvantaged.
44.	Page 13. Clause 4.iv: can we assume a consolidate demand will be shared with the suppliers to produce and keep in stock and will Lower shelf life below 85%?	This could be a proposal to respond to "Projects to deliver Strategic Objectives". However note that many countries have rigid remaining shelf life requirements
45.	Will TGF share any format with suppliers for periodic reporting with key points on which TGF expect us to share information?	Yes – the general scope of periodic updates and reporting is outlined in the following Sections of Schedule C1: draft Strategic Partnership Framework Agreement • Section 8: Supplier contract management performance monitoring. • Section 5.3: Allocations in Subsequent Periods The reporting formats will be similar to the Schedules E1-E3 of this RFP. However, the Global Fund reserves the right to revise the scope and format of reporting.
46.	Please clarify the evaluation criteria for re-allocation of FPP volumes (in case of a FPP supplier inability to deliver) to other FPP panel suppliers.	Refer to section 5 of Schedule C1: draft Strategic Partnership Framework Agreement: Allocated and Committed Volumes

47.	Common labelling Discount- is it referring to the special labelling requirement or AWs harmonisation e.g. country specific artworks vs universal labels.	Yes – the discount available for standard labelling without any customisation
48.	PAHO usually requires the submission of technical documentation – please advise if this will still be the case	Yes, if not already submitted, technical documents will need to be submitted and reviewed by the PAHO Quality Assurance team including: 1. WHO Prequalification letter. 2. Certificate of Pharmaceutical Product (CPP) according to the WHO certification scheme 3. Formal declaration by the Bidder indicating the National Drug Regulatory Authority (NDRA) responsible for lot release of the finished product. 4. Proof of therapeutic equivalence reviewed by the NDRA of the country of manufacture is required. 5. Manufacturing sites requirements: List of all sites involved in the manufacturing process 6. Product insert (pamphlet) and the primary, secondary and tertiary packaging, including diluent (if applicable) in all four of the requested languages (English, Spanish, Portuguese, and French). 7. The current finished product specifications, including diluent (if applicable), approved by the corresponding NDRA. 8. A summary of the stability studies for natural and accelerated storage conditions performed according to international recommended standards for the offered product category (i.e., pharmaceutical, biological). The summary should include result tables and conclusions for three different lots of the presentation offered. 9. Most recent Periodic Safety Update Report (PSUR). 10. List of countries where the product is registered and has been granted a marketing authorization.