Geneva, March 29, 2022

Request for Proposal TGF-D-00014

Subject: Clarification questions to all prospective bidders – Round 1

#	Questions	Answer
1	Kindly clarify the point on purchase order and strategic framework agreement. Are there any specific products which will be supplied under purchase order agreement?	Please see Section 1 in the Request for Proposals TGF-D-00014. The Global Fund will offer two types of framework agreements which are differentiated by the type of engagement and level of allocation and commitment: 1. Strategic Partnership Agreement 2. Purchase Order Agreement The bidder selects either a Strategic Partnership Agreement or a Purchase Order Agreement, it is not specific to any products.
2	Please clarify why no forecast is available in Schedule F Demand Forecast for products listed under “Product Scope”	This is due to currently limited demand visibility for these products

3	Please clarify how suppliers can enter pricing for a product manufactured at one site but supplied from a) the same manufacturing site directly or b) a distribution center.	As indicated in the Request for Proposals TGF-D-00014 (page 12: Schedule E2: Commercial Template), Bidders who wish to offer products from more than one manufacturing site located in different countries and at a different base price shall complete a separate Schedule E2 template for each site.
4	In "Technical Schedule E1.2_Country Coverage", we wonder if we could fill products which registration dossiers has been submitted but MA hasn't been received? if yes, could we make comments in column F after select product name and country, and leave all other cells in blank? if not, could you specify the way to provide the products' submission information?	Please only submit products with active registration, or previously registered and under renewal process.
5	We found our product Artemether/Lumefantrine 60/360mg 6 tablet dispersible, pack of 30 blisters, WHO MA155 was not included in the E1.1 Product Coverage, could you add it and update the file?	Any product not covered in the E.1.1 Product Coverage can be included as a note in the comment box.
6	We have new products in pipeline, could we fill our new products in E1.4_Strategic Project form	Please indicate the pipeline product under the Schedule E1.1 Product Coverage. If the product is not listed, please include them in Column Z under “Comments.”
7	Regarding innovative products request you to share examples if any for supporting docs to be submitted	Supporting documents should be submitted to provide evidence of the current development stage.
8	Few products we are working on the API and will be developing the FPP next year. Will these products be eligible for commercial & technical submission?	Please see instructions under Technical Schedule E1.1_Product Coverage on pipeline products and innovative products.
9	As per section D point 2, it is mentioned that bidders have to fill schedule E templates (E1 & E2) separately for each manufacturing site. Please advise if this rule applies to facilities within same country (as we have products to offer from several facilities in India) or only if manufacturing sites available in different countries for e.g., in India and countries in Africa.	Please refer to Section 3 E.10 of the Request for Proposals TGF-D-00014.
10	TGF is already working on country registration database, will this portal be live before the tender closing, or will the bidders have to fill the standard excel format that we use currently.	Bidders will have to fill the Schedule E1.2 Country Coverage.

11	Referring to page 23 table 1, the API Supplier signs yearly contracts with Artemisinin manufacturers in China on yearly basis and formulation suppliers submit these contracts to TGF. As per the criteria mentioned in RFP, manufacturers having 36 Month contract will get more allocations. But a formulation manufacturer will not be able to sign a contract with Artemisinin suppliers directly. Please can you clarify how this works and rationale for this criteria?	Please refer to Table 1 in page 23 of the Request for Proposals TGF-D-00014 with regards to the question on allocation. Please refer to Figure 3 on page 24 of the Request for Proposals TGF-D-00014 to understand the linkages between FPP Panel Suppliers and Panel Artemisinin Manufacturers.
12	The products have been segmented into strategic products, mainstream products & limited use products. Some of the new products not yet approved or in the pipeline such as TAF/E/D 25mg/200mg/50 mg, DRV/r 400mg/50 mg, ADL 600mg/50mg/300mg have been categorized as limited use. Does this mean these products will have low demand in the coming years and suppliers should plan their capacities accordingly for these products during launch and scale up?	For the 3 new products: TAF/E/D 25mg/200mg/50 mg, DRV/r 400mg/50 mg, ADL 600mg/50mg/300mg, there is currently low demand visibility. The Global Fund will however work closely with suppliers through the RFP implementation period to provide more transparency.
13	Can we quote for products which are being filed in Q3-Q4 2022?	Please see instructions under Technical Schedule E1.1_Product Coverage on pipeline products and innovative products.
14	For Semi Synthetic Artemisinin, both pricing and availability have been an issue and even now there is a substantial pricing difference, can we quote 2 different prices for SSA and non SSA antimalarials?	This will not be possible. Please refer to Page 24, paragraph 9 of the Request for Proposals TGF-D-00014.
15	Technical Schedule E1.2_Country Coverage: •There are limited cells available for mentioning registration status of all ANTMs and for all countries. We need more rows having pre-filled data (yellow coloured cells) to accommodate all countries and products. •We understand that the requirement mentioned in Column “L” – Retention P.Date means Retention Paid date.	You can insert new rows for Schedule E1.2_Country Coverage. The drop-down list works. You will need to copy the formula for the item code. Retention P Date means Retention Paid Date.
16	Page no:6: Section 3.A.1: Intention to bid… We could not locate where we need to click and express our intention to bid. Please advise.	Bidders must advise whether their company intends to submit a proposal by clicking on the “Yes” or “No” button which will be at the end of the email you will receive automatically through our TGF Sourcing Application.

		Please click on the following URL to access the TGF Sourcing application: https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/. On the Sourcing application, please check the notification bell in upper right of the screen, there are buttons 'Accept Invitation' and 'Decline Invitation'. Select the button 'Accept Invitation' if you wish to participate to the RFP  Please open the following link in your browser to see the step guide: Step guide
17	Page no: 10: Section 3.F.4.c: Each technical and commercial element is linked to the Global Fund's "Balanced Supply System" principles… Request you to please elaborate "Balanced Supply System" principles. Are these the same 5 principles presented to us during the tender consultation meeting on 15th February. If otherwise, please advise.	The supplier consultation slide deck on February 15th is available in the public domain. The "5 Balanced Supply System" principles are articulated in greater detail on Section 4, Figure 2 of the Request for Proposals TGF-D-00014.
18	Page no: 10: Section 3.F.5.c: Proposals will be evaluated against the criteria defined, and Bidders will be ranked in order of evaluated scores, using a normalization algorithm to score Bidders relative to each other. The scores will then inform the first year of allocation, if any. Please explain the normalization algorithm.	Bidders are evaluated through a defined methodology approved by the Evaluation Panel, in line with Global Fund's procurement principles and rules.
19	Page no: 9: Section 3.D.4: "Only reservations or requests for amendments to the Strategic Partnership Agreement or Purchase Order Agreement submitted by Bidders as part of their proposal may be considered by the Global Fund. These reservations or requests for amendment will be taken into account in the overall evaluation." Please elaborate. Does this mean we can ask for a revision in the agreement clauses?	Limited non-material changes to the agreements (Strategic Partnership Agreement or Purchase Order Agreement) may be considered by the Global Fund only if these are raised as part of Bidders' submission to the RFP. These reservations/amendment requests will be taken into account during the proposals' evaluation and must be included in the comment box under Schedule A: Officer's Certificate of Conformance and Acknowledgement.

20	Page 11. Section 3.F.7. Schedule E1: Technical Template, 6. On time in full delivery. OTIF is the evaluated information. Please confirm if we need to present historical OTIF scores and share in our bid submissions?	Please refer to page 13, Section 3, F.9 Schedule E1 (f) in the Request for Proposals TGF-D-00014
21	Page 12. Section 3.F.9.a: Finished Pharmaceutical Products not compliant with the Global Fund's Quality Assurance Policy but submitted and accepted for review by the WHO Prequalification Programme, a Stringent Drug Regulatory Authority or the Global Fund's Expert Review Panel should be reported under Pipeline Product in column V and W of the Schedule E1.1_Product Coverage. A proof of submission has to be submitted. Which proof we shall give for a product that is under development but not yet submitted to WHO/SRA for evaluation?	Supporting documents should be submitted to provide evidence of the current development stage.
22	Page 17. Section 4.A.4.a: Pooled demand. Please advise if new countries are getting added in the PPM country list where we might need to focus on registrations.	Please refer to the PPM country list under Technical Schedule E1.2 Country Coverage.
23	Page 26. Section 4.D.7: The Global Fund will allocate product volumes (including committed volumes in some instances) by distributing the total allocated volume among successful Bidders in proportion to their relative scores and subject to any overall caps established and any identified implementation challenges. Please share details of established caps.	For clarification, caps are intended to ensure that any additional volume above the annual allocation volume is monitored internally at the Global Fund.
24	Page 37: Product set 4: Pipeline products Please share the strengths of all the products in the list. Also, Artesunate injectable 60mg is in Product set 1: Strategic products as well. So, are the strengths in Product set 4: 30mg and 120mg?	You can indicate details in the comments section under Column G Artesunate injectable products of all strengths are considered strategic products.
25	Page 38: Schedule D. Product set 2: Mainstream Products, item code 25625: Dolutegravir/Lamivudine/Tenofovir alafenamide 50/300/25 mg tablet, container of 30 tablets - no carton	TAF/L/D is currently not included in WHO guidelines but is recommended by WHO for children (as an alternative) and for adults (in special circumstances).

	This product is not in the WHO guideline yet. Will Global Fund procure this product as this product is included in the mainstream product list?	The product is eligible for Global Fund procurement.
26	Page 43: Schedule F: Demand Forecast for ANTM Demand for Sulfadoxine + Pyrimethamine 500/25mg Dispersible tablets are not included. Please advise.	We are not differentiating dispersible from hard tablets for this product. Please refer to the demand for Sulfadoxine + Pyrimethamine 500/25mg (3 tablet 100 blisters) under Schedule F.
27	Page 43. Schedule F: Demand Forecast for ANTM Product strength and demand for below mentioned products are not included. Please advise the reason for the same. i. lower strength Sulfadoxine + Pyrimethamine 250/12.5mg Dispersible tablets ii. Primaquine 15mg	During the RFP implementation we will work with manufacturers for low demand products to ensure continuous supply where required.
28	Page no: 25: Section 4.c:-Pharmaceutical Product sets -"Group 4-Phasing out products" In this point it is mentioned that "No need of additional suppliers". Is this reason why phasing out products like Efavirenz 600. Lamivudine 150mg and Lamivudine oral solution are not mentioned in this RFP.	Lamivudine oral solution is in the Product Scope under "Product Set 3: Limited use Products." Efavirenz 600mg and Lamivudine 150mg are low demand products, which will be phased out in the coming RFP cycle.
29	In the Schedules - excel sheets provided, we are unable to "WRAP text" the information in cells. This can create problem at time of printing these excel sheets as incomplete information will get printed. Can we get excel sheets with WRAP text option available?	If required, you can add extra information in the comment box.
30	Regarding volume allocations and commitments for FPP Panel Suppliers for artemisinin-contained products linked to long term agreements, due to price volatility Artemisinin vendors are not willing to enter into an LTA for three years with our API vendors. Please let us know what will be the consequence if we are unable to furnish three years agreements?	Please refer to the Table 1: Volume allocations and commitments for FPP Panel Suppliers for artemisinin-contained products linked to long term agreements to be established with Panel Artemisinin Manufacturers on page 23 of the Request for ProposalsTGF-D-00014

31	Page no.13: d.iii: Africa Footprint Can a company submit a proposal for a product manufactured at a contract manufacturing site in Africa which is SRA approved or is in a pipeline to get SRA approval?	For projects to deliver on strategic objectives, you can only submit a proposal which meets the Global Fund's Quality Assurance Policy.
32	With respect to the templates in Schedule E.1 (technical) and E.2 (commercial) we are unable to access the certain drop down list in certain categories. Some drop down work and some don't, which make it very difficult to use and understand. Due to above we are unable to edit as per the drop down requirements. Request you to please provide us the password for locked files or provide the unlocked templates which will be much easier for us to take forward.	In case of any technical issues, please contact the technical support through the "message" function of the Sourcing Application.
33	Is GF planning to reduce special labels considering implementation of MTS (Make To Stock)?	Yes