Geneva, April 29, 2022

Subject: Clarification questions to all prospective bidders – Round 2

General questions

#	Questions	Answer
1	Rapid Supply Mechanism – What will be the minimum required shelf-life for RSM supplies?	RSM has the same shelf-life requirements as standard orders i.e. >/= 75% remaining shelf-life on delivery in country.
2	In Schedule F, Demand Forecast for ANTM – The number of packs 2023 mentioned for Artemether + Lumefantrine is equivalent to 100 Million treatment?	Yes
3	Africa footprint - We have facilities in Africa. One facility manufactures ARVs for the local market with large market share of TLD in the country of the facility. However none of these facilities are WHO PQ or SRA approved. We would need to make certain investments to get the regulatory approvals which we are prepared to do. But the product cost would still be higher than if we supply from outside Africa. The RFP documents do not clarify the exact benefit if supply is made from Africa. So we do not know if the additional investments that we need to do and the increased cost of the	Please refer to 'TGF-D-00014 RFP Tender Document_Pharmaceuticals' section 3, F (Evaluation of the proposal)

	product will lead to additional business for the company or whether if it would be detrimental for us. So would it be possible to get clarity of the exact benefit for this criterion	
4	Liposomal Amphotericin - We do not see any projection for the product. Can we assume that it will not be required in the next RFP?	During contract implementation we will work with manufacturers for low demand products to ensure continuous supply where required.
5	Page 20 of the RFP states "Moving towards a make-to-stock model to mitigate supply fluctuations" as an objective. Would it be possible to get more details of the same	This will be addressed during the implementation phase.
6	Concerning RFP TGF-D-00014 I would like to ask if the following documents need to be submitted also by suppliers who already have an active Framework Agreement with The Global Fund. SCHEDULE A - Officer's Certificate of Conformance and Acknowledgment SCHEDULE B - Confidentiality Agreement SCHEDULE H - Integrity Due Diligence (IDD) questionnaire	Please refer to 'TGF-D-00014 RFP Tender Document_Pharmaceuticals' section 3. D. New and existing suppliers are required to submit the same documents. With the exception of Schedule B (optional Confidentiality Agreement), all listed schedules must be submitted
7	Regarding to the 36 months contract with Artemisinin supplier, what's the requirement of the dates? Should it be a contract cover 2023-2025? Or we can use current contract which has 3 years validation? Is the 36 months contact with SSA also needed? Because the SSA supplier may reject to sign such contract with us.	Please refer to the Section B (5) Table 1 in the RFP document. The contract covers 2023-2025.
8	If we wish to offer products from different facilities located in different countries at a different EXW price (products is all from one	Yes

	manufacturing site in one country), should we submit separate Schedule E2 template (e.g. 1 country in 1 template)?	
9	PEPFAR has removed Dolutegravir/Lamivudine/Tenofovir alafenamide 50/300/25 mg tablet from priority and kept Dolutegravir/Emtricitabine/Tenofovir alafenamide 50/200/25mg tablet as priority product, we have noticed in this tender Dolutegravir/Lamivudine/Tenofovir alafenamide 50/300/25 tablets added in mainstream product list, is this mentioned erroneously, kindly confirm.	TAF (L/D and E/D) are currently not included in WHO guidelines but are recommended by WHO for children (as an alternative) and for adults (in special circumstances). Both products are eligible for Global Fund procurement.
10	In Schedule F Demand Forecast, the indicative annual demand forecast for 2023 of Artemether + Lumefantrine is given as 3,333,335 packs. Please clarify whether this is pack of 30 treatments. Also can you provide the quantity distribution of 30x6, 30x12, 30x18, 30x24 and those of the higher strengths like 40/240, 60/360 and 80/480? Similarly in Schedule F, SCM Campaign Amodiaquine + Sulfadoxin- Pyrimethamine tablets' forecasted volume is 1,900,000. Can you clarify whether this is packs, if they are packs, what is the pack size considered here and also give bifurcation of quantities per strength. In Column V, W & X of E1.1 we can indicate Pipeline Products. We have some products which are under development for which BE Study is going on. Can we include these products in our submission although we do not have proof of submission to WHO or SRA. In absence of these, what proof will be acceptable to you? This question was raised by someone in the first round, but the response given against question #21 does not clarify the matter clearly.	Demand forecast for Artemether + Lumefantrine is in 30 blisters. The volume is correct for Amodiaquine + Sulfadoxine- Pyrimethamine, in packs of 50 blisters. The breakdown of strengths is not available yet. Please indicate pipeline products under Schedule E1.1 Product Coverage. If the product is not listed, please include them in Column Z under "Comments" and clarify the stage of development. No supporting documents are required at this stage.
11	We have questions on the cost sheet: - Cell of Line 31- S/T/U, Line 34 -S/T/U, couldn't show out the data.	The issues have been addressed in the amended schedules. If there are further

	- When revise data in column R from line 29-34, auto formular in column S is changing in the line above. E.g. when I revise data in line 34 cell R, the data in Line 33 cell S changed accordingly, which is incorrect. - Auto calculation of Cell of line 52-R and line 53-R is in correct. We couldn't get the same figures with the formular. - Cell of line 70-K, we couldn't input 0 as there is no other non-active ingredient.	concerns, please contact the support team through the platform.
12	Please be informed that drop down in this given sheet the text is not getting wrapped (column E) and is interfering with other cells . Please can you help to share the sheet with wrap text option. Looking forward to hear from you on the same.	This will only affect the printed version in pdf. As we also have the item code, the product can be easily identified and the template can be filled as it is.
13	Hello, the column J of Schedule E.1.1 doesn't take numbers and an error message pops up the value doesn't n match the data validation restrictions defined for this cell. I am not sure whether this happens only to me, but I tried several times to re-download the documents. Can you please advise what to do?	The technical issue was corrected in the amendment published on April 11th
14	We are expected to share the prices for 2023-25 while being in the middle of the 2022. As you are aware, there could be changes in raw material prices or other issues which could positively or negatively impact price. Would there be a mechanism to relook at the prices during the contract period? This could be beneficial for Global Fund as well	As indicated in the RFP document, pricing for 2023 will be used for evaluation. Pricing for 2024-2025 is for information only. A pricing review will be part of the implementation.
15	Queries related to IDD questionnaire: Details We have following queries	Yes, please disclose current or recent contracts with the Global Fund or the Global Fund's Principal Recipients, including ARV supply under framework agreements, if any. For contracts other than ARV supply please mention

	Q1: Does “5b. Prior engagements“ related to ARV product supplies from our company to Global Fund ?	the contact person or department at the Global Fund.
16	Q2: Difference between 8a. List three of the Bidder’s former or current clients and 8b. List three of the Bidder’s former or current business partners? Kindly clarifies us asap	Clients refers to entities who are purchasers of pharmaceutical products. Partners refers to entities that hold any other relationship, such as suppliers, joint venture partners, consortium members, licensors, related companies within the same holding.
17	In E1.2 ANTM PPM Country List, countries like Kenya, Ethiopia, Rwanda, Myanmar, Gabon, etc. are not appearing. Will the country list be revised to include such countries.	These countries are Global Fund eligible countries but are not currently in the PPM country scope.
18	For Technical Schedule E1.3_Supply Security and Visibility, SECTION B. Should we fill KSM/intermediate which only produced by our own, or we need to get the all API information from our API supplier to fill the cells?	All the information should be provided for both in-house and externally procured, KSM, intermediate and/or APIs.
19	Q1: On page 9, E.5: It is mentioned that Schedule E3 too Bidders have to submit. We couldn’t locate Schedule E3 in the tender documents. Please share.	There is no Schedule E3 as the bidders are required to enter the information directly on the platform, as indicated in Section 3 D (1). Please check the Requirements step on the Sourcing application and populate the fields in the section #4 “For Information and Implementation Proposal”.
20	Q2. Schedule E1.1: Product Coverage, pipeline products. If we receive approval of the pipeline product by the end of December 2022, will GF consider and allocate quantities for that product.	Allocation for 2023 will only consider eligible products at the time of submission.
21	Thanks for your response on clarifications for Round 1, please find our next set of clarifications. - Schedule E1.5 - Please advise if the schedule E1.5 to be submitted separately for each country if for suppose local presence is in multiple countries.	Please submit only one template of Schedule E1.5 in which you indicate all the African countries where you are operating
22	If, the bidder is engaged as supplier only for pharmaceutical products exports in the GF	Yes, this can be disclosed in aggregate as provision of pharmaceutical products, unless a particular category, formulation or brand forms

	jurisdiction should it be reported in the section 5A,5B,5C? Awaiting your response	more than 20% of the total sales, in that case please list that category, formulation or brand. Please also provide the approximate value of the exports, to the nearest $1million.
23	Ritonavir 100mg tablet, pack of 30 tablets is listed. Can we bid for 60 pack size or are we limited to only 30's?	Please only submit for packaging under the RFP product scope (E1.1 - Product coverage)
24	Schedule E1.2: In country coverage, do we have to add list of countries (that is part of PPM countries) but where the product is not registered?	There is no need to add the list of countries where the products are not registered, or dossier submitted
25	Schedule E1.1: In product coverage, Section A under product description, we have to add lines for new products which we intend to file to WHO in the near future and for whom there are already a couple of players in the market but it is currently under development with us. Can we give details in the pipeline products section for such products after mentioning the product name in the product description and keeping all the other cells empty?	Same as answer for Question #21 of the Round 1 as below: 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.”
26	Can you please confirm what exactly is the definition of pipeline products? Is it that the products are near to filing or filed but not approved yet or do we have to include under development products too (products which are not specified in the Innovative products' list too, example, Artesunate rectal capsules etc)?	In section A of the schedule E1.1 Product coverage, in the columns V to X, you can inform about any pipeline products within the product scope which have been already filed, In section B, please indicate if you are developing any of the innovative products listed in that section. If you wish to inform about any other products which are not listed in sections A and B, please include them in Column Z under “Comments.”
27	The tender no where mentions if we have to quote for Primaquine 15mg tablets. This product is not pre-filled in both the excel sheets- Schedule E1.2: In country coverage nor in Schedule E1.1: In product coverage and also we are not allowed to insert this product in any of these excel sheets manually. This product strength is missing in Schedule D-Product Segmentation too. Please advise.	This product is not part of the RFP product scope. In case, you develop this product, please include them in Schedule E1.1: Column Z under “Comments. During the RFP implementation we will work with manufacturers for low demand products to ensure continuous supply where required.

28	We need a clarification in Schedule-H IDD questionnaire page number 9, there is a request above point no. 6 Bidder's ethics and Integrity Programme 'This submission should be made in spreadsheet form as a separate file'. Will you please confirm if submission is pertaining to point 6 or point 5c	The 'spreadsheet' comment is within point 5c, and refers to that section, not to the following section 6
29	With respect to Point No. 5 under Section F of the tender (Page 10 of the tender document), kindly let us know the criteria for evaluation and respective weightages within the said algorithm.	We do not disclose the weighting criteria
30	With respect to Point No. 7 under Section F of the tender document (Page 11 of 45), kindly share the weightages of the respective parameters under technical evaluation (Elements 1-6 of Schedule E1) and commercial evaluation (Elements 1-4 of Schedule E2).	We do not disclose the weighting criteria
31	For Point No. 8 under Schedule H, kindly advise the difference between Client and Business Partner in Sections 8a & 8b respectively.	Clients refers to entities who are purchasers of pharmaceutical products. Partners refers to entities that hold any other relationship, such as suppliers, joint venture partners, consortium members, licensors, related companies within the same holding
32	Countries such as India, Kenya, South Africa, Botswana are not there in the drop-down list of countries in Schedule E 1.2. Kindly advise how do we enter our registration details in these countries.	See answer for Question # 17 above.
33	In the tender response, while you are seeking information of trilingual packaging, please clarify if the ability to do trilingual packaging would be taken into considering during the tender evaluation.	It will be considered during the contract implementation period.
34	We have below few questions regarding current tender. Would appreciate swift response on same.	Forecast for this item is listed under Schedule F

	Abacavir/ Lamivudine 120/60mg tabs 30's packs demand forecast is missing in Schedule F, would appreciate receiving the same.	
35	Product coverage file E1.1 has Darunavir combination for strength Darunavir/Ritonavir 400/50mg tabs of 60's packs, could you help us with more details on pipeline products/ strength for Darunavir/Ritonavir 600/100 & 800/100mg respectively.	For those strengths, you can indicate them in the comment's box
36	Can more products be added under innovative products in product coverage file.	Any product not covered in the E.1.1 Product Coverage can be included as a note in the comment box.