Issue Date: 15 April 2014

Subject: REQUEST FOR PROPOSAL (RFP) TGF 014-010

Round 2 Questions and Responses

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

No	Question	Response
1	Could you please clarify ACT forecast volumes under Co-payment Mechanism for 2014. Under Schedule F: Co-payment Funding and Demand Levers for 2014 has been only given.	The ACT forecast volume for the Co-Payment Mechanism for 2014 is based on the funding provided either through the separate AMFm Channel or through the grant for the relevant countries, the subsidy level and demand levers established by the recipient countries. Using this data we expected manufacturers to calculate their own volumes of product based on the pricing which they plan to submit.
2	In Bii Section 2: Quality and performance 2.1 customer History: We have not supplied this product under AMFm but before and after getting WHO prequalification we have supplier this product in our brand name to private market. Please clarify if we can give Customer History of our past supplies to any customer in private market or to MOHs. Also, please let us know if we can give details of our WHO prequalified Anti-TB products which we have supplied to GDF under "STOP TB Partnership with Global Drug Facility"	The Global Fund will not use delivery data supplied from manufacturers. It is not uncommon for manufacturers not to have previous delivery history and in this circumstance a mathematical figure will be applied in this section based on the opinion of the Proposal Evaluation Committee to ensure suppliers are neither, advantaged or disadvantaged. The customer history is only relevant for the product category being tendered.
3	In Bii Section 2: Quality and performance 2.2 Quality performance & 2.3 Delivery performance: Can	The Global Fund will not use quality data supplied from

No	Question	Response
	we give the details of all the inspections & supplies (if any) for the reference product (AL) done in past 3 years, even if it is by any In-country authorities or supplies in private market. In the instruction on Right Side of the sheet: it is mentioned that "we will be accessing your quality performance over the past 3 yrs and we will take this information from our internal data. We have included this field for information only and you do NOT need to enter any data." Please clarify on this as we believe in our case Global Fund will not be having information of our company in their internal data.	manufacturers. It is not uncommon for manufacturers not to have previous quality performance and in this circumstance a mathematical figure will be applied in this section based on the opinion of the Proposal Evaluation Committee to ensure suppliers are neither advantaged, or disadvantaged.
4	In Bii Section 2: Quality and Performance 2.4: PPM Country Registrations: Our product is registered or under-registration in countries with our Brand names with packsize 6x1(one blister containing 6 tabs), 6x2 (2 blisters containing 6 tab each), 6x3 (3 blisters containing 6 tabs each) and 6x4 (4 blisters containing 6 tabs each) packsizes. Please clarify to supply under PPM or co-payment mechanism, these registration would consider valid. OR please let us know if (a) we will have to file variations with the registration authorities of different countries for additional packsize registration i.e, of 1x12 (single blister containing 12 tabs), 1x18 (single blister containing 18 tabs) and 1x24 (single blister containing 24 tabs). (b) We will have to re-register in generic name i.e, Artemether 20mg + Lumefantrine 120mg tabs	<u>General requirement:</u> The Global Fund is not requesting for any additional registration either for pack sizes or generic names. The following is provided as additional information. Products that meet the Global Fund requirements should ONLY be quoted. This refers to (a) WHO Prequalified OR (b) Approved by any Stringent Regulatory Authority OR (c) ERP reviewed with a validity date active at the time of responding to this RFP. The packaging and units per pack should be the same in all respects as that of the approved product by WHO Prequalification Medicine Programme or SRA or ERP as the case might be. If the packaging and unit per pack are not yet approved so as to meet the Global Fund requirements, the manufacturer can, at its discretion file variation with the respective institution as the case might be, meaning if the product was approved by WHO Prequalification Medicine Programme, then the variation should be submitted to WHO Prequalification Medicine Programme and likewise. However it is mandatory that the variation should have

No	Question	Response
		been accepted at the time of responding to this RFP. The manufacturer can register the product either in the brand name or in the generic name. However it should be ensured that only products that are approved by the above mentioned authorities and that meet GF requirements are supplied. It is recommended -that the product is registered in the country at the time of responding to this RFP. If not yet registered, -it is highly recommended that the manufacturer initiate the registration process as early as possible.
5	In Bii Section 1: Company and product 1.2 Product details of ACTs being proposed: We have marketed this product in our brand name "Lumiter" but is WHO pre-qualified in Artemether 20mg + Lumefantrine 120mg tabs, Can we mention both the names under Product name? Also under Treatment Forms: our packsize is 1x6, 1x12, 1x18 and 1x24's in which we would be supplying if we get an order. Can we mention these pack size?	Yes it is permitted to use both names. However it should be ensured that only those products that are approved by the above-mentioned authorities and that meet GF requirements are supplied. Yes the pack size should be mentioned, but only the pack size prequalified by WHO PQ or SRA authorised will be considered. It should be ensured that the labelling of the packs (primary and secondary) and pack inserts should be as it was submitted to the above mentioned approving authority.
6	.4 Manufacturing Capacity: Please clarify what do you mean by "is the total installed capacity capped"? Also, We have to specify Lead time in weeks for 0.5M treatments: Please clarify which treatment size we should consider infant (6 tabs), child (12 tabs), adolescent (18 tabs) or adult (24 tabs) to achieve the total number of tablets.	In business some manufacturers determine the maximum amount of business they wish to undertake with specific customers. If the business of your organization takes this perspective in its level of business with the Global Fund you might set a cap on the amount of manufacturing capacity, your organization is prepared to dedicate to ACTs. If so we would like to know what that figure is. When calculating lead times we anticipated that potential suppliers would take a perspective that covered all treatment types. If you want to be more specific please use the adolescent (18 tabs) figure or total number of tablets.

No	Question	Response
7	Could you please clarify all the countries under PPM. Under Schedule E: total 6 countries are specified however in Bii Section 2. PPM country registrations total 43 countries are mentioned. Are the 43 countries the total countries which falls under PPM.	The full list of countries, which form the PPM, is listed at Appendix A to this document. 6 countries are shown in Schedule E as this is the total number of PPM countries, which have so far a demand forecast for ACTs in 2014. 43 spaces have been left in the PPM registration field as it was felt that this was the maximum space needed.
8	Also please let us know when we can sign the confidentiality agreement between us and Global Fund. Can we also do it post tender closing? But in this case can we get assurance that our information will not be shared or made publicly available during e-auction or negotiation phase.	You may sign the confidentiality agreement at any time from now on including post-tender closing. A word version was posted with Amendment No 1 posted on the solicitation web page. Whether you sign the confidentiality agreement or not, the Global Fund has no intention of sharing your detailed pricing with any third party (including other manufacturers or partner agencies). Depending on the final structure of the potential reverse auction, it is possible that other parties may see your bid price if you are the lowest bidder but it will not be associated with your name. The reverse auction is a mechanism to finalise the base price and will not be structured on a 'winner takes all' basis.
9	In regard to submit our offer please clarify along with Schedule A: Certificate of Conformance, Schedule Bi & Bii (PDF as well as excel) do we have to submit our product artworks and any other document as well.	If you have not previously supplied the Global Fund there will be no record of your artwork and you are therefore requested to submit copies in pdf format. No additional documentation is required at this stage.
10	In regard to Bi, 1.1 Initial Price (Base Price) / PPM packaging or Co-payment Mechanism: Hospital Packs comprising 30 individual treatments – Does the pack contain individual patient leaflet? Please be informed our packing is 30 treatments (blisters) directly placed in a carton with single leaflet. Thus we do not	Hospital packs are generally packed with total number of blisters and one patient leaflet

No	Question	Response
	have individual leaflet and monocarton for each treatment. Thus in this case our answer would be NO for first two questions. Please confirm if we can put the combined price of one leaflet and one bigger outer carton against "Price of Hospital pack secondary packaging"? But because this packaging (single leaflet & one Outer carton) is applicable for 30 treatments, should we divide combined price of single leaflet & one Outer carton by 30 and then put the figure in cell to arrive at "total product cost per pack" which is (a+b1 or b2). Please advise on this.	Suppliers are required to provide the price of a complete hospital pack. The packaging and units per pack should be the same in all respects as that of the approved product by WHO Prequalification Medicine Programme or SRA or ERP as the case might be.
11	Please also advise on Bi, 1.1, Co-Payment Mechanism Packaging Individual Packs: "Do individual packs have 2 levels of secondary packaging?"	Some companies may choose to have two levels of secondary packaging and this field has been added to cover that eventuality.
12	Point 1.4 on Conditions for RFP Participation, page 5 Point 7: Please clarify what is meant by "the Global Fund may, at any stage of this tender…d) accept alternate proposals or price submissions"	Should the Global Fund so elect, it may accept alternate proposals or price submissions for ACTs.
13	Point 2.3 on Product Volumes, page 7 Please clarify whether a rolling forecast (monthly or quarterly) per country could be provided to successful bidders following allocation of PPM volumes.	It is the intention of the Global Fund to provide as much information as possible regarding future demand to panel suppliers. A quarterly update is a possibility and this can be discussed as part of the framework agreement discussions.

No	Question	Response
14	Point 2.6 on Contract Management, page 8 Point 3: Please clarify precisely what lead time shall be taken into consideration for « specific order as per committed volumes »	As it is the intention that committed volumes will be for an extended period, it is anticipated that manufacturers will manage their own lead times to meet their commitments. This clause is intended to protect the Global Fund's principal recipients if it becomes evident that this is not possible.
15	Point 3.2 on Communications during RFP, page 10 Please clarify the function that will hold the position of negotiation coordinator and Event Administrator for Stage 2 and please confirm that an independent adjudicator will monitor such proceedings.	The Negotiation Co-ordinator and Event Administrator is a member of the Global Fund's Sourcing Department. Their role is to facilitate the delivery of both the negotiation rounds and the reverse auction and to act as a point of contact for all communication during stage 2. With regard to independent adjudication we would draw your attention to section 1.4 Para 8, and we further note that there will be no independent adjudicator.
16	Point 3.5 on Evaluation Criteria for Stage 1 Management, page 11 Please clarify the functions participating in the Proposal Evaluation Committee and please confirm that an independent adjudicator will monitor such proceedings.	Regarding an independent adjudicator, please see the response to question 15, above.
17	Point 4.1 on Product and Packaging Requirements, page 15 Point 1: Please define precisely what is meant by "sound international practices".	In this context 'sound international practices" refers to an approach that has been acknowledged by a number of countries as being the most appropriate way to achieve the objective.

No	Question	Response
18	Point 3c: Please confirm whether "pharmaceutical storage container" means primary and/or secondary packaging. Moreover, it is indicated that the pharmaceutical storage container must meet the requirement of having pictorial administration instructions. However, this has never been required previously and therefore is neither on our primary or secondary packaging. Please reconsider this requirement or accept to waiver this requirement.	An answer to this question will be provided as early as possible. Please note that the language in the RFP is as per the language in each of the fully executed Master Supply Agreements for the AMFm: "Minimum Packaging and Labelling Requirements".
19	<u>Point 5.2 on Notification of Decision of Allocation of Product Volumes and Contracting, page 17</u> Point 2: Please define the time period considered as "protracted" i.e. 1 month, 6 months? Moreover, in the case of protracted or unsuccessful negotiations and in order to avoid the unilateral approach of the Global Fund "taking action at its discretion…including…re-allocating the proposed allocation to another proposed Panel Supplier" we request that an independent arbitrator be nominated to consolidate and arbitrate on potential issues common to all Panel Suppliers with regards to the Framework Agreement.	The Global Fund has not defined "protracted" for this purpose. The approach to the new framework agreements is intended to be collaborative, and protracted in this context will be defined as the length of time before the Global Fund realises there is little hope of finding agreement. Where there is a will by both parties to succeed, an extended period of time to agree caused by different geographies or available resources would not be considered protracted. With respect to contractual negotiations, reference is made to Section 1.4.3 ("This RFP in no way obligates the Global Fund to award a contract…") and 5 (Legal Matters).

No	Question	Response
20	Point 6 on Legal Matters, page 17 Point 7: Whilst we shall, of course, fully cooperate with the Global Fund on any past, present or future fraud investigations, we consider that we have the right to challenge the methods or results of the investigation, as is the case with any investigation. Please take this into consideration in the wording of this point (for which, may it be reminded is legally binding).	The Global Fund will not change the language in the RFP Section "Legal Matters".
21	Response Template: Bi Section 1.1, PPM and Co-Payment Mechanism Packaging tables: Please specify whether the data on packs per pallet (column M) is required "ex-works" or as delivered to customers.	Suppliers should provide the information regarding number of packs per pallet based on ex-works packaging.
22	Section 1.1, Additional Cost Elements table: Does the column L entitled "Revised total cost per pack" require the revised total cost of secondary packaging (i.e. secondary packaging cost in column J + additional cost) or revised total cost (i.e. primary packaging cost + secondary packaging cost + additional cost)?	Please enter the total revised cost per pack (i.e. primary packaging cost, secondary packaging cost and additional cost)
23	Response Template: Bii Section 1, Point 1.4, Manufacturing Capacity table: Please clarify:	

No	Question	Response
	- whether the Available Capacity should include forecasted volumes for Global Fund - which lead time in weeks is requested for the 0.5M treatments (e.g. lead time ex-works or lead time including delivery to customer warehouse).	The available capacity should not include any forecasted volumes for the Global Fund. Please provide the lead time information ex-works.
24	Section 3, First Line Buyer information: In the instructions, it is indicated "Please enter the value of Co-Payment Mechanism shipments by year to the listed countries indicating which First Line Buyer received the product". Please clarify whether this should correspond only to the value financed by the Global Fund or whether it should correspond to the total value per shipment (i.e. Global Fund + 1LB).	Please provide the information for the value financed by the Global Fund.
25	**Schedule F - Co-Payment Funding and Demand Levers for ACTs for 2014** Table 1 – Forecast Available Funding: Please specify whether the amounts indicated are the amount co-paid by the Global Fund (i.e. including freight and excluding contribution of 1LB)	The values shown are the amounts co-paid by the Global Fund including freight and excluding 1 LB contribution.
26	**Schedule H - Form of Confidentiality Agreement** In the context that the "Purpose" is described as the sharing of information for a potential transaction (i.e. during the tender process), please clarify whether this confidentiality agreement will cover any other confidential information that is provided post-tender or whether confidentiality clauses shall be integrated into the Framework Agreement.	Confidentiality provisions will be included in the Framework Agreement. They will be substantially similar to the confidentiality provisions in the existing AMFm Master Supply Agreements.

<table>
<tr><th>No</th><th>Question</th><th>Response</th></tr>
<tr><td></td><td>.</td><td></td></tr>
<tr><td>27</td><td>In Schedule B ii, product and company, we are not able to put our company complete details/address in the rows, as the format cells are restricted with the certain number of alphabets only. Request you to kindly un-restrict & provide the flexible format to furnish our details completely.</td><td>The protection on the document is not password protected and can be removed by yourself if you require. However if you have insufficient space in the product and company section please feel free to add the additional information in the additional notes section at Row 86.</td></tr>
<tr><td>28</td><td>In Template Bii Worksheet “Product and Company” Point No. 1.2 Product Details of ACTs being proposed. Please confirm if the data required are to be filled in the following format.

<table>
<tr><td>Reference Product Set (See Tender Document Section 2.2)</td><td>Artemether-Lumefantrine ("AL") 20/120 mg. Non-Dispersible Tablets</td></tr>
<tr><td>Treatment Forms</td><td></td></tr>
<tr><td>6*4 (Band 4)</td><td>Brand Name 20/120</td></tr>
<tr><td>6*3 (Band 3)</td><td>Brand Name 20/120</td></tr>
<tr><td>6*2 (Band 2)</td><td>Brand Name 20/120</td></tr>
<tr><td>6*1 (Band 1)</td><td>Brand Name 20/120</td></tr>
</table></td><td>That is fine.</td></tr>
<tr><td>29</td><td>If we are offering all the three reference product sets like AL Non Dispersible, AL Dispersible and AS-AQ do we have to fill three different template of B ii comprising of five worksheets for each reference product set.</td><td>No. We suggest you complete the following for each product reference set but do not duplicate information unnecessarily.
1. Product and Company
2. Quality and Performance
3. First Line Buyer Information.
One Submission for the value proposition and RSM options is</td></tr>
</table>

No	Question	Response
		sufficient.
30	In Template B ii Worksheet "Quality and Performance" Point 2.1 Customer History - please confirm what is the UOM for quantifying the no. of treatments. Do we have to consider the no. of treatment as pack of 6 tablets as a treatment or a pack of 24 tablets as a treatment?	Consider a pack of 6 tablets as a treatment.
31	In Round 1 Questions and responses in Point No. 43 you have referred to a confidentiality agreement as in Schedule H to be signed before April 10th.Please confirm whether this is mandatory to be completed before 10th April. However, we have scanned and forwarded a signed Confidentiality Agreement in PDF format for your signature.	Completion of the Confidentiality Agreement by 10th April is not mandatory. We acknowledge receipt of your signed copy and it will be returned signed by us as soon as practicable.
32	Ref to Tender document Page 9 – Point 3.1 b Stage 2 and subsequent to Round 1 Questions and responses Point No. 01 you had responded that in the negotiation process GF will not ask manufacturers to match the prices of others. So please confirm what would be the procedure for reverse auction for finalize the pricing. Whether in this case the global fund will inform the offered price of one manufacturer to all others.	If the reverse auction process is used competing bidders will be able to see the lowest price offered and their own ranking in the bidding. All bids will be anonymous and the decision to match the lowest bid will remain with individual manufacturers.
33	What is the definition of "most favoured nation" by Global fund.	Kindly refer to answer 12 in the Round 1 Q+A.
34	As per the Annexure A, there is a printing error under Section 5 which is Volume Allocation and Initial Contracting is wrongly mentioned as Legal Matters.	You are correct Legal Matters is Section 6. We shall issue an amended version of Schedule A to correct this.
35	Can we mention two product details in one template	Yes, If it is very clear which elements of data apply to which

No	Question	Response
	considering less amount of data is available for one product.	product.
36	Costing template- Explain taxes and duties required in the template.	In the past we have discovered that some taxes and duties have been liable on the import and export of product and materials. We therefore included this section. If it is not applicable in your circumstance then leave this field blank.
37	Under Quality and Performance tab in Schedule Bii: (1) 2.3 Delivery Performance, will this be based on VPP and AMFm. There are specific situations where oversights or otherwise from other entities, even PFSCM, caused our deliveries to miss the delivery date. How can we be certain that these scenarios will not be marked against us?	Should you submit a proposal in response to the RFP, and address this issue in your proposal, we will endeavor to investigate the situation, if required and take it into consideration
38	Under Rapid Supply Mechanism tab in Bii Under option 1 and 2: Does the commitment required refer to the quantity total in schedule G? Should that just be copied over? For Max No of Treatments, if we can not supply the "full" amount, should the amounts be in the same ratio as schedule G? If not, is it suggested?	We would refer you to the instructions on the right hand side of Schedule Bii. This says Note B: This is the volume of commitment required from the Global Fund to achieve the proposed option without additional cost. If you cannot supply the full amount you are free to determine the ratios that work best for you.
39	Will RSM always be packed in Hospital (Bulk) packs? If not, should we assume for this submission?	For the submission assume that RSM volumes will be in hospital packs.
40	Under Quality and Performance tab in Schedule Bii, 2.5 Non-PPM: it mentions non-PPM are part of the RSM	It says that the analysis may be part of the RSM. At this point in time RSM is being designed to support PPM and Non PPM

No	Question	Response
	analysis. Please confirm if it only limited to countries in CPM and PPM. Also, we would like that have a growing impart on RSM. Our response to Rapid Supply Mechanism will be limited to only countries where we have registration now. How will in change as we gain registration in more countries? Will The Global Fund request more coverage? Can we offer it? And what effect will it have on future orders outside of RSM?	countries. The framework agreement has mechanisms to adjust committed volumes on an annual basis. However specifically regarding the RSM it is difficult to draft the precise terms until we know what manufacturers will propose.
41	Given limited number of current registrations, will our quantity total be evaluated based solely on those countries versus the entirety of schedule G?	It will be evaluated on a mix of the two. We are currently working on harmonising packaging and investigating ways of expediting registration should product be required in an emergency.
42	Regarding Freight Costs: (6) Please confirm the type of containers that The Global Fund will require for shipment. Will Reefer Containers be required for any/all types of shipments? Land and/or Sea? By country?	All ACTs have stability studies for class IV (Long Term condition: 30°C / 65% RH 9Rate of humidity) and Accelerated condition: 40°C / 75% RH). According to the package the ACTs should be stored below 30 degrees. ACTs could be transported in regular containers but it has been the policy of PFSCM to ocean ship those products in reefer containers. Standard conditions have been used for airfreight. This policy will continue. Please note that some co-payment mechanism countries have included a demand-shaping lever to specify that shipments by sea are to be prioritized (e.g. Nigeria).

Appendix A to Questions and Answers Round 2

PPM Countries. (Please note not all these countries are in receipt of ACTs)

Bangladesh	**Cameroon**
Indonesia	**Cape Verde**
Pakistan	**Guinea**
Philippines	**Guinea-Bissau**
Thailand	**Mali**
Vietnam	**Niger**
Mozambique	**Senegal**
Tanzania	**The Gambia**
Uganda	**Armenia**
Zambia	**Georgia**
Zanzibar	**Macedonia**
Cote d'Ivoire	**Colombia**
DR Congo	**Dominican Republic**
Ghana	**Guatemala**
Nigeria	**Guyana**
Benin	**Honduras**
Burkina Faso	**Nicaragua**
Burundi	**Bhutan**
Congo	**Cambodia**
Liberia	**Lao PDR**
Malawi	**Mongolia**
Sierra Leone	**Nepal**
Central African Republic	**Papua New Guinea**
Djibouti	**Sri Lanka**
Mauritania	**Timor Leste**
Togo	**Mauritius**
Yemen	**Swaziland**
Angola	**Comoros**

Fiji: which acts a medical store for itself and the following countries
(For ARV)

Cook Islands,
Federated States of Micronesia
Kiribati
Nauru
Niue
Palau
Republic of the Marshall Islands
Samoa
Solomon Islands
Tonga
Tuvalu
Vanuatu