

Issue Date: 3 April 2014

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

Round 1 Questions and Responses

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

No	Question	Response
1	Please confirm if there are different price offered by different manufacturers, then whether the lowest price will be informed to other manufacturers under the negotiation process asking them to match their prices with the lowest price OR the allocation will be given on different prices of different manufacturers.	The negotiation process will not ask manufacturers to match the prices of others. Each manufacturer will be given the opportunity to refine their proposal and then submit a Best and Final Offer. The allocation process will therefore be undertaken based on the different pricing from different manufacturers.
2	Once the price is accepted and the quantities allocated to various manufacturers under the PPM, whether the GF will raise specific purchase orders for manufacturers to various countries as and when GF receives requirements from those countries.	Specific purchase orders will be raised by the Global Fund's Procurement Service Agent (PSA), which for ACTs is PFSCM. Whilst the PSA will place orders as far in advance as is possible, purchase orders will be raised as and when required. Each such Purchase Order will be pursuant to the terms of the Framework Agreement between the Supplier and the Global Fund and count as a drawdown against any Volume Commitment by the Global Fund to that Supplier.
3	Once the price is accepted and the quantities allocated to various manufacturers under the Co-payment mechanism whether the manufacturer has to call for the POs from first line buyers on quarterly basis or yearly basis. If there are multiple first line buyer then what will be the ratios of	The POs from First Line Buyers will be required to be submitted on an annual basis with proposed deliveries staggered throughout the year; in response to a specific request from the Principal Recipient in the country, these may need to be re-submitted (e.g. if a subsidy rate should change, if the PRs informs the Global Fund of a change in the list of participating first line buyers). The available funding for co-payments is country-specific,

	quantity allotment to each first line buyers.	and the Global Fund receives guidance from PRs regarding demand-shaping levers to apply when allocating the available resources across the participating first line buyers. A manufacturer must be prepared to fulfil the orders as submitted to the Global Fund; however, the Global Fund will inform the manufacturer of the quantities which will count as a draw-down against any Volume Commitment by the Global Fund to that supplier. This may be done on a quarterly basis or on a longer-term basis.
4	Under the Co-payment mechanism, if any particular manufacturer has more number of first line buyer in the country than the other manufacturer, where he will get the advantage of more allocation based on the number of first line buyers.	This has been the case historically. Going forward, on a country-by-country basis, the number of First Line Buyers will continue to be one of the considerations when reviewing and potentially accepting the proposed commitment levels. Additional factors include previous history and alignment to country-specific demand shaping levers as communicated to the Global Fund by the Principal Recipient.
5	If there is more than one Pre Q manufacturer for any product, please confirm whether GF will also consider the offer of manufacturer having ERP.	For products with more than two pre-qualified suppliers, ERP approved suppliers will not be considered in this tender. If there are only one or two pre-qualified suppliers, the Global Fund reserves the right to consider the offer from an ERP supplier.
6	For PPM and RSM, please clarify whether preference will be given only to the manufacturers having product registration in receiving countries OR whether GF will consider giving orders even to the manufacturers who does not have the product registration.	Registration will not affect selection as a PPM Panel Supplier, however, for the allocation process, manufacturers must have their product registered in at least one of the PPM countries, thus the overall allocation will take in account registration status of the product. For PPM the PSA will only place orders for countries with manufacturers who are registered in that country. The position for RSM is still being evaluated, but preference will be given to the products with higher registration status.
7	In Point 3.6 Stage 2: Procedures Sr.no.7 (page 14) reads that the reverse option will be supplied to bidders by Wednesday, 16 th April - Please reconfirm if this date is correct.	Wednesday 16 th April is the date by which the Global Fund will provide details of the operational aspects of any proposed reverse auction. The date when the decision to use a reverse auction is made is 8 th May. The difference is designed to allow manufacturers adequate time to prepare
8	During the meeting of manufacturers on 13 th March 2014 and also in the presentation it was informed that the maximum allocation of Dispersible tablets to any one	You are correct. The RFP document contains an error. The actual allocations are as follows:

	<p>manufacturer will not be more than 75% whereas, in tender document page 8 (2.5 .1 supplier management) the maximum percentage of allocation for Dispersible tablets is mentioned as 40%. Please confirm the correct percentage of maximum allocation.</p>	<p>a. AL Non dispersible products 40%</p> <p>b. AL Dispersible products 75%</p> <p>c. AS-AQ products 40%</p> <p>This has been reflected in the amendment to the RFP posted on the Global Fund's website.</p>
9	<p>In Bi 1.2 freight cost, you have asked for price per pallet (LCL) however please note that since GF wants to send the goods by Reefer container the LCL facility will not be available. The manufacturer has to take the FCL. So how the cost is to be worked out.</p>	<p>Do not complete section 1.2 Reefer but rather insert the price of a FCL to each of the destination ports in free format in the Additional notes section line 73.</p>
10	<p>In Schedule Bi General Instructions at Point 4 B you have mentioned that we can add a new line in excel by pressing Alt + Enter but we find that it is not possible.</p>	<p>The Alt +Enter command allows you to add an additional line within a cell when typing text. If you want to add a new line to the overall template you will need to unprotect the worksheet add the line and then re-protect the worksheet.</p>
11	<p><u>Point 2.4, page 7</u></p> <p>Please explain what points i. and ii. mean, notably the notions of “underwritten” and “further grant management activity”</p>	<p>Underwritten: This means that the committed volume of products is guaranteed to be purchased during the time period.</p> <p>Further grant management activity: This covers allocated product where the volumes are still at the planning phase and have yet to be finalized and will not be underwritten by the Global Fund.</p>
12	<p><u>Point 2.7, page 9</u></p> <p>Point 2: It is indicated that “Pricing will be reviewed between the Global Fund and individual suppliers as part of the annual commitment process”. Does this mean that the validity of prices submitted in this RFP is limited to 12 months rather than the two-year term as indicated in Point 1.1.1 (page 3)?</p>	<p>The Supplier will be required to sell products at the Pricing for a two-year period.</p> <p>However, the pricing will be reviewed as part of the annual commitment process to ensure that any unforeseen circumstances are accounted for. A review does not imply any commitment to a change in the pricing.</p>

	Point 4: Please explain the meaning of “most favored nation”?	A most favored nation clause will be included in the framework agreement. Essentially this states that if the manufacturer offers better pricing or terms to any other customer during the term of the agreement then the Global Fund may avail itself of those same terms and pricing.
13	<u>Point 2.8, page 9</u> Point 3: Please explain the notion of “underwrite”	Underwrite: In this context the term means to guarantee delivery of the products.
14	<u>Point 3.4, page 11</u> Point 2.B: In the past, all prices for PPM or Co-Payment Mechanism were in both currencies, USD and EUR. In addition, the financing pledges given to the Global Fund from the European Commission (France, Germany, Ireland, Italy, Luxembourg, Netherlands,) amount to 2.37 billion EUR and represent 26% of the total pledge. For this reason and in the context of highly volatile exchange rates, we strongly recommend the Global Fund to reconsider the possibility to quote in EUR as well as USD.	As stated in the RFP, this tender is conducted in US Dollars.
15	<u>Point 3.5, page 12</u> Point 2: Please explain precisely upon which basis price proposals will be compared bearing in mind that the cost of the transport is an important parameter depending on geographical region (i.e. European GDP regulations) and packaging volumes. Point 4: Please explain precisely what is meant by “non-commercial” elements Point 7: Please clarify, in a similar manner to the tables for the Commercial and Technical Evaluation, the objective criteria and weighting for assessing the “most favorable	Base prices are evaluated based on the terms expressed in the tender namely FOB. Overall cost of freights is considered as part of the allocation process (see definition of total landed cost). Non-commercial elements refer to those elements of the proposal that do not have a direct financial implication. The evaluation of the RSM proposals is designed to ensure the highest integrity and the quickest response at the lowest cost. Precise evaluation criteria will be defined to achieve these objectives but will not be made

	option”.	public.
16	<p><u>Point 3.6, page 13</u></p> <p>Point 1: Please explain precisely what is meant by “pricing elements not subject to the auction” and “non-priced elements will be negotiated”</p> <p>Point 7: Please note that the date of Wednesday 16th April is incoherent with the date provided in point 3.6.2 which is 8th May.</p>	<p>If held, the auction will focus on specific element of the price. For example, the auction could focus on tablets in primary packaging. In that instance, the cost of the secondary packaging and other elements not auctioned would comprise the “pricing elements not subject to the auction”.</p> <p>Non-priced elements refer to any part of the proposal that does not include a price.</p> <p>Please refer to the answer to Q7, above.</p>
17	<p><u>Point 4, page 15</u></p> <p>Point 4.1.4: Please explain precisely what is meant by “special requirements” requested by Buyers.</p>	<p>Some countries have made specific packaging and labelling requests and this phrase refers to those special requirements.</p>
18	<p><u>Point 5.1, page 15</u></p> <p>Point 2C: Please define precisely the notions of “available capacity”, “total landed cost”, “validated First Line Buyer commitments”, “Country Registration” and “Alignment to RSM requirements”</p>	<p>We assume these questions refer to page 17.</p> <p>Available capacity: The available manufacturing capacity of the plant as expressed in number of treatments that can be manufactured in a given period.</p> <p>Total landed cost: The cost of the product, freight and insurance to the port of arrival.</p> <p>Validated First line Buyer commitments: The level of First Line Buyer Commitment as reviewed and, if necessary, modified, by the PEC, based on</p>

		<p>alignment to demand levers and previous history.</p> <p>Country Registration: Countries have specific registration requirements for importation of health products. The allocation process will take into account a manufacturer's registration with countries where the products will be delivered</p> <p>Alignment to RSM requirements: Although evaluated separately the RSM volumes will be linked with the other volumes in the allocation process. This is to ensure that there is practical and feasible way of coordinating the procurement of ACTs through the different delivery channels.</p>
19	<p><u>Point 6, page 17</u></p> <p>Should our legal department have any queries regarding the Legal Matters (Terms & Conditions), at which point in the process should this be addressed i.e. during the second round of questions or in the proposal submission, as with the Form of Framework Agreement?</p>	<p>If your legal department has queries regarding the legal terms in the tender these should be forwarded to Anne-Sophie Salmon as soon as possible as adherence to these is a requirement for acceptance of your tender.</p>
20	<p><u>Response Template: Bi</u></p> <p>Please note that ASAQ Hospital Packs are comprised of 25 treatments per pack rather than 30.</p>	<p>Thank you. This will be factored into the evaluation process.</p>
21	<p><u>Response Template: Bii</u></p> <p>Section 1, Point 1.4 (Manufacturing Capacity): Please clarify what you mean by “point of constraint in manufacturing process”</p>	<p>Typically in a manufacturing process some stages have greater capacity than others, and the stage that has the least capacity is the point of constraint.</p>
22	<p>Section 2, Point 2.1 (Customer History): Please clarify what you mean by “largest three customers” i.e. customers within the Global Fund initiative or all our customers for all products?</p>	<p>This refers to all customers and not just those within the Global Fund initiative, but only relates to the specific products being tendered.</p>

	Section 3: Please note that the majority of our shipments between 2010 and 2013 were in EUR. For this reason, we shall indicate 1LB value of shipment data in EUR (cf. statement n° 1.4 regarding point 3.4)	Understood and acknowledged.
23	Schedule C – Form of Framework Agreement between the Global Fund and Panel Suppliers Please provide ASAP the template Framework Agreement	We are planning to issue this document the week commencing 7 April.
24	Schedule D - Summary of Key Amendments to Existing AMFm Master Supply Agreements Please provide ASAP the template Key Amendments to Existing AMFm Master Supply Agreements. Should our legal department have any queries regarding the Key Amendments to Existing AMFm Master Supply Agreements, at which point in the process should this be addressed i.e. during the second round of questions or in the proposal submission, as with the Form of Framework Agreement?	We are planning to issue this document the week commencing 7 April. These should be submitted with your proposal as for the Framework Agreement.
25	Schedule F - Co-Payment Funding and Demand Levers for ACTs for 2014 <u>Table 3 – Demand Shaping Levers for all Countries</u> Please clarify which period (e.g. 2010-2013 or just 2013) will be taken into account for the demand shaping lever « Performance of manufacturers ».	Schedule F is not intended for use to assess manufacturers prior performance. It is intended to provide a guide to manufacturers to enable them to align their First Line Buyer Commitments to these demand levers. This alignment will be validated by the PEC.
26	<u>Table 4 – Country-Specific Demand Shaping Levers</u> Nigeria – Transport by Sea vs Air: Given that European GDP directives will require the sea transportation of medicines using “Reefer” containers and the fact the ACTs are very	

	<p>sensitive to hot temperatures and high humidity, we strongly recommend the mandatory use of “Reefers”.</p> <p>Nigeria – First line buyer pipeline: Please clarify what is meant by “Subject to FLB submission of periodic reports to Private Sector Co-payment Mechanism country secretariat”.</p>	<p>Acknowledged.</p> <p>Going forward, Nigeria will be requesting that First Line Buyers submit certain information in the form of a report to a dedicated office of the PR in Nigeria (i.e. the Private Sector Co-payment Mechanism Secretariat). These reporting requirements are being finalized at present and will be incorporated into First Line Buyer Agreements to be signed between the PR and the Buyer. It is expected that this will provide the PR with visibility regarding the distribution network of each First Line Buyer, which may inform the PR’s guidance to the Global Fund regarding relative approvals to be made across participating First Line Buyers.</p>
27	<p>Schedule G - Rapid Supply Mechanism Demand Profile for 2014</p> <p>Please specify the ratio between individual treatments and hospital packs in the RSM demand profile.</p>	<p>The RSM mechanism is designed to support the PPM and therefore products should preferably be in hospital packs however the main focus for this proposal should be on the primary packaging.</p>
28	<p>Schedule H - Form of Confidentiality Agreement</p> <p>Should our legal department have any queries regarding the Confidentiality Agreement, at which point in the process should this be addressed i.e. during the second round of questions or in the proposal submission, as with the Form of Framework Agreement?</p>	<p>Please send a marked up copy of the confidentiality agreement to Anne-Sophie Salmon at your earliest convenience.</p>
29	<p>Payment terms are not mentioned in the RFP does this mean it’s flexible and they’ll be as per our offer.</p>	<p>The baseline payment terms are currently as per PFSCM for PPM orders; and the private sector co-payment mechanism. However the tender is designed to explore flexibility in this area and should you feel you could</p>

		offer additional financial advantage through more favourable terms please enter this in the additional discount section.
30	For Bid submission, do we need to mark a copy to you Mrs. Anne-Sophie Salmon, Sourcing Manager; Sourcing Department. anne-sophie.salmon@theglobalfund.org ? or submit only to Solicitation@theglobalfund.org	Please submit your proposal to solicitation@theglobalfund.org
31	In section 3.4 Stage 1 Preparation and Submission , it is mentioned that signed copy of all submissions in PDF format. Do we need to print all submissions in our company's letter head?	There is no requirement to submit all proposals on company headed paper. We request PDF format as an additional check against inadvertent alteration during the evaluation process.
32	Can offer be made if PQ/ERP approval is expected latter during the year. If yes what's the cut off date.	Please notify us of your expected PQ/ERP date in the value proposition section. However, potential qualification as a supplier will not be factored into this year's allocation process.
33	The bid document says that 80% of the 1 st year volumes will be allotted at the time of contracts. Can you please confirm if the break down will be at country level or at 1 st line buyer level?	The allocation will be at country level.
34	On Uganda have seen that all 1 st line buyers are full with stock and most are reluctant to pick up the product at the new co-payment % of 50% and 70%. In this case will global fund reassess the new strategy?	National authorities have set the co-payment levels and sufficient flexibility has been built into the allocation process to cope with changes in demand pattern. For this reason we will not be re-assessing our strategy at this time.
35	On supplier measurement, what's the exact criteria going to be used as we have a very short performance record.	Supplier performance measurement will be assessed against two criteria. 1. The total number of orders shipped on time against the vendor commit date over the total number of orders shipped. 2. The total number of orders that pass quality inspection and testing over the total number of orders inspected.

36	We were informed by AMFm that it has exemption for MAS stickering and were not informed of the cut off date. But when we were ready with the shipment it was told that MAS is required. Our whole month's production had to be repacked causing delays Will this be held against us in performance.	First Line Buyers should have been aware of the date of the expiry of the waiver and should have informed suppliers of the requirement. However, we will consider this specific MAS requirement in Nigeria separately when reviewing manufacturer performance
37	We consider our product costing proprietary information and would not like to share the same, kindly remove this request.	We understand the proprietary nature of some of the information requested which is why we have offered you the option of signing a confidentiality agreement with us.
38	The Artemisinin price has historically been very volatile. With the tender being for 2 years is there an option for a price revision under the contract if not is there an exit clause for suppliers.	<p>The tender states that there will be a review of pricing after 12 months and this will be reflected in the framework agreement. This is designed to address any unexpected eventualities but does not imply a firm commitment to re-negotiate prices. The framework agreement specifies the termination clauses to the contract.</p> <p>Vendors are free to propose other value options in their submission in addition to the core requirements</p>
39	<p><u>Schedule Bi.</u></p> <p><u>In Section 1 for Artemether –Lumefantrine 20/120 mg Non dispersible-</u></p> <p>a. As per point 1.1 Initial Price, pallet price has been asked for both PPM and Co-payment. For co—paid orders, goods are not palletized. Can we leave this column blank?</p> <p>b. As per point 1.2 Freight costs, Price per pallet (LCL) CIP Port of Arrival has been asked– we do not palletize the shipments and we only use FCL for Global fund shipments. Can we provide non palletized FCL freight cost of a single pack instead?</p>	<p>Yes, but please indicate why you have done so in the additional notes section.</p> <p>Yes</p>

40	<p><u>In Section 1 for Artesunate – Amodiaquine fixed dose combination (2.7 AQ-AS ratio)-</u></p> <p>a. As per point 1.1 Initial Price, PPM Packaging & Co-payment mechanism Packaging- Hospital packs comprising 30 individual treatments has been asked. We supply ASAQ in packs of 25 treatments. Can we quote as per our pack size? Further in co—paid orders, goods are not palletized. Can we leave this column blank?</p> <p>b. As per point 1.2 Freight costs, Price per pallet (LCL) CIP Port of Arrival has been asked– we do not palletize the shipments and we only use FCL for Global fund shipments. Can we provide non palletized FCL freight cost of a single pack instead?</p>	<p>Yes quote as per your pack size.</p> <p>Yes, but please indicate why you have done so in the additional notes section.</p> <p>Yes.</p>
41	<p>As per the instructions to fill Section 2- Co-payment commitment volumes, commitments should align with Schedule F of the tender document. Can you please clarify whether the distribution of the ratios is value based or volume based?</p>	<p>The ratios expressed in table 4 are for volumes of product (i.e. number of treatment doses).</p>
42	<p><u>Schedule B ii</u></p> <p>1. In Section 1, point 1.2, it is mentioned that treatment forms refers to pack size (eg- 6*1). Individual treatments are 1*6, 1*12 which are packed in box of 30's thus making the pack size 30*1*6, 30*1*12 etc. Can we mention this pack size?</p> <p>In Section 3, First Line buyer information- do we have to enter the shipments made to public buyers like MOH, NMCP etc or only to private first line buyers?</p>	<p>Yes if it aids the clarity of your submission.</p> <p>Please enter the information for all First Line Buyers both public and private.</p>

43	We need a Confidentiality Agreement in place, can you confirm this could be countersigned before Apr 10 (attached a PDF)? – Schedule H, the original has been sent to you already	Yes this will be countersigned and returned prior to 10 April.
44	Could you please publish the draft Framework Agreement, as the RFP's document refers to it?	We plan to publish this the week commencing 7 April
45	The Forecasts in Schedule E and F don't show any demand for Dispersible, is this correct? If so, what volume would you commit to?	Forecast demand does not differentiate between dispersible and non-dispersible product. In the AL-Dispersible reference product set the Global Fund will separate the demand forecast for dispersible product according to the country requirement. The Global Fund will commit to the volume subject to the individual supplier caps as shown in the tender and as amended at Q8.
46	Could you please share the Summary of Key Amendments to Existing AMFm Master Supply (schedule D)?	We plan to publish this the week commencing 7 April
47	Schedule Bi, it is not clear where to enter the selling price per pack-size, could you please define?	Lines 17 and 18 define the product cost in primary packaging. We then add the secondary packaging cost to establish the overall sales price dependent on packaging at L22 and 23, L27 and 28, and L32 and 33. We assume that the price of secondary packaging includes those elements of overhead, manufacturing and profit that relate to it and we do not require these to be broken out.
48	On Page 24 of the RFQ, Schedule E shows the PPM ACT Forecast Volumes for 2014. For Malawi, there is a display of the bands totaling 0 packs/treatments. On the same table, Uganda is missing. What is the difference between showing a "0" total and being left off the Schedule.	Malawi and Uganda are at different stages of their planning cycle hence the difference in reporting style. However at the moment neither has a forecast requirement. If further requirements are added these will be managed through the allocation process
49	Regarding the Technical Evaluation, could you clarify whether there is a word limit on the Value Proposition section? If so, please provide the limit.	While there is no specific limit we would recommend that you are concise and to the point. However suppliers are reminded that a separate document is also acceptable and that they ensure they include all information they feel is relevant as the Global Fund can only assess the information within the

		submission. Suppliers are also at liberty to provide further supporting information if they feel it strengthens their value proposition.
50	<p>We have supplied ASAQ FDC in 2013, but due to the analysis method transfer test result from NIDQC was finally successful in November 2013 and the sampling for re-testing was finished in early 2014, goods was shipped out in December 2013 and January 2014 though production was finished on time in August 2013.</p> <p>We noticed that one of the evaluation criteria is “Historical quality and delivery performance”, so we are worrying if the situation in 2013 will make a negative influence in our quotation this year.</p>	Should you submit a proposal in response to the RFP, and address this issue in your proposal, we will endeavour to investigate the situation, if required and take it into consideration
51	<p>Product and Company Clause 1.2 - As defined by MMV –Is your company listed under the following heading</p> <p><i>Query - We have checked the website mentioned by you, however could not find the relevant information. Request you to kindly guide us further for this response.</i></p>	The MMV website lists projects and companies developing new medicines in the fight against malaria. It does this under four headings. If your company is not listed then from MMV’s perspective you are not developing any new product and your answer should be no.
52	<p>Clause 1.4 – 1. Manufacturing Capacity</p> <p><i>Query – Request you to clarify whether the Total Installed Capacity is for the treatments or the manufacturing site as a whole. Secondly if it is for the product, then please elaborate on the ‘Installed Capacity Capped’</i></p> <p>2. Define the point of constraint</p> <p><i>Query – Kindly elaborate more on the specifics required.</i></p>	<p>The total installed manufacturing capacity refers to the maximum number of treatments for the tendered products that can be supplied.</p> <p>The capped capacity question has been inserted because some manufacturers may put a maximum limit on the volume of ACTs they wish to manufacture.</p> <p>Please refer to the answer to Q21.</p>

53	RSM <i>Query – There are four options provided in the sheet and bidders have to propose various alternative options possible. Kindly advise if we have to propose 4 options or only 2 options.</i>	<p>The number of options proposed is up to the manufacturers. The Global Fund has suggested two potential options and left space for two further options for manufacturers to propose their own ideas.</p> <p>The Global Fund expects interested manufacturers to propose at least one option.</p>
54	Schedule Bi Pricing AL Clause 1.2 – Freight cost <i>Query – The freight requested is Price per Pallet (LCL), wherein we would like to know whether palletisation is required or the freight is required per shipper for each</i>	<p>Palletisation is not mandatory. The Fund was proposing to use this field to calculate the cost of freight per pack. If you can calculate this yourself please insert the costs in the additional notes field clearly stating the cost for each type of pack in secondary packaging i.e. (PPM in hospital packs, Co-Payment in hospital packs and Co-Payment in individual packs.</p>
55	We would like to know if there is any requirement of supporting documents to be provided with regards to regulatory or technical.	<p>This is not required as part of the tender submission and should we require these documents we will request them separately.</p>