

## CLARIFICATIONS TO RFP-DAN-2023-503604 – Supply of Paediatric and Adolescent Cancer Medicines

No.	Bidder(s) Query	UNICEF Response
1	<p>The current cancer estimates provided are insufficient to assess volumes required by medicine, given the lack of specificity re: cancer types being treated. Can the estimates be made more reliable? Have estimates been calculated already (total, by region, by country)?</p>	<p>The Initiative aims to provide treatment to 5,000 children in the first year and 10,000 children in the second year for the following six cancers: acute lymphoblastic leukemia, Burkitt lymphoma, Hodgkin lymphoma, retinoblastoma, Wilms tumor, and low-grade glioma. These six cancers together represent 50–60% of all childhood cancers and are mostly curable when diagnosed early and managed with proven therapies.</p> <p>The estimates cannot be made more reliable as the treatment protocols will vary by region, country and even hospital.</p> <p>The purpose of the tender is to establish Long Term Agreements (LTAs) “blanket agreements” against which an actual Purchase order will be placed upon receipt of actual demand. At this point UNICEF is looking to receiving as many offers as possible for the products listed in order to enter into multiple agreements (LTAs) with suppliers. The agreements to be signed will not be Country Specific, i.e. will be for global supply starting with the initial 6 countries (Nepal, Jordan, Zambia, Uzbekistan, Mongolia and Ecuador).</p>
2	<p>Who will be the receiving organization? UNICEF and PAHO to a central location, or is delivery expected to each site?</p>	<p>The receiving organization will be the consignee indicated on each Purchase Order. The incoterms are FCA named Seaport/airport. The suppliers will hand over the goods to a UNICEF or PAHO designated Freight Forwarder at the named port who will then arrange for delivery to the final destination.</p> <p>Where the products require cold chain during transportation, and in order to maintain and monitor the cold chain, Proposers need to ensure that the correct packaging <b><u>is included in their offers.</u></b></p> <p><b>Please note</b> that the Freight Forwarders <b><u>do not</u></b> do additional packing at the time of receiving the shipment.</p>
3	<p>Many products do not have WHO prequal, but in general there will be bidders that hold SRAs. Isn't the burden to accept SRA registration a matter for the country to address, rather than the bidder?</p>	<p>This is required for the technical assessment of the products for recommendation for procurement. Please see Section 3. Statement of quality on page 10 of the tender document.</p>

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4	Is the tender considered 'winner takes all' or will there be a tender split (e.g. 70/30) to ensure requirements can be met in the absence of supply by one party?	The intention is to award multiple Long term arrangements against which actual purchase orders will be issued. The purchase orders will be issued taking into consideration parameters such as: how soon the goods are needed in the recipient country, registration status of the product in the recipient country, if supplier is able to offer other products requested by the recipient country etc.
5	The quantity/ pack number request does not match a commercial pack size (e.g. 5 pack requested vs a 10 pack registered). Is a bid with alternate pack sizes possible?	Offers for alternative pack sizes of the same medicines are welcomed. <b>Please see slide 36</b> in the Webinar Power Point Presentation on how to include offers of different pack sizes in the Commercial Offer Form ( <i><b>Annex D in the Solicitation Document</b></i> ).
6	One of the product requests is not available in our medicines list (within a medicine). Are partial bids accepted?	Yes, partial bids are accepted as indicated on <b>page 23</b> in the Solicitation document under Section 15.6.2 "Partial Proposals"
7	The LTA is written as 12 months + possible 12 month extension. The extension period may include the addition of the six follow-on countries. Are tender bids meant to accommodate the possibility of six new countries being added (as yet unnamed and no volumes accounted for)?	The extension period refers to the validity of the agreement that will be signed which will be a "time bound agreement" as opposed to a "target bound agreement" which indicates the target quantity to be purchased with the signed agreement. With a "time bound agreement" any country supported by UNICEF/PAHO can be accommodated so long as the request is made within the validity period of the agreement. Refer to the Background (Section 1) and Purpose (Section 2) of the tender in the Solicitation Document (page 8 and 9).
8	Will medicines recently added to the EML and within the tender period be added to the tender bid request? This was new knowledge that occurred during the tender, and at least one of those medicines is an alternative to the current medicine (I will also note that in the EML application, it was noted that the cost per regimen of one of the recently approved addition to the EML was shown to be routinely lower than the current medicine – that could be a material saving to the Global Platform fund).	Medicines recently added to the WHO EML and are recommended for the treatment of any of the six paediatric cancers targeted by this Tender have been added to the List of Products in the Solicitation Document - <b>Please see Amendment No. 1 of the Solicitation Document.</b>
9	What is UNICEF expectation in regard to maintenance of regulatory information that we will provide for this tender? In case of any changes in regulatory data do we	Yes, you need to inform UNICEF via e-mail of any changes. <b>Please see page 22</b> of the tender document, under Section 15.5. Special Technical Instructions - sub section 15.5.1.

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	have to inform UNICEF? If yes in what form are we expected to do that.	
10	Are all relevant labels and documents (product insert, instructions for use etc) to be provided to the tender countries in English?	<p>At this stage, for product assessment purposes, all labels and documents should be provided in English. It is fine if label and leaflet have additional languages to English. Customization of the language may be required at the time of placing the actual purchase order depending on the recipient country requirement and this will be clearly communicated to the LTA holder before placement of Purchase Order.</p> <p>Please feel free to notify us in your Proposal Submission if you already have product in language(s) relevant for the 6 initial countries mentioned above in the response to Query #1 .</p> <p>Please also see <b>Section 8: Language, page 15</b> of the Solicitation Document.</p>
11	Our product has regulatory approval in some but not all of the tender countries. Is a single label preferable for supply (e.g. US label, US stock) for all countries, or is there an expectation to supply locally-approved products in participating countries?	<p>SRA approved label/leaflet text in English is required for product assessment. If SRA approved text is in another language, labels and leaflets translated to English with Declaration of equivalence should be provided.</p> <p>Please let us know if you have the same SRA approved product locally approved in any of the 6 countries. We are in discussion with the 6 countries on modalities to ensure early access in the pilot phase if product is not registered in recipient country. <b>See slide 41 of the webinar presentation.</b></p>
12	<p>We note ‘documents may be requested at a later date’; e.g. CPP. Documents like a CPP may have a significant lead time.</p> <p>Is a model CPP helpful to provide within the tender proposal, and a current document provided (with appropriate lead time) on request?</p>	For the initial submission, any recent CPP for the specific product is acceptable. In the case of an award, new CPP might be required depending on the final country destination requirements.
13	If a product is approved in the target country, will UNICEF/PAHO be allowed to use a pack from another country, or is the pack approved by the Regulatory agency required?	See the response for question 11

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14	Can we participate in this tender if the medicine does not have regulatory approval in country?	Yes, you can participate in this tender. Please see page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria.
15	If the product has a regulatory approval, does the proposer need to be the MAH in the country?	No, but the proposer has to have authorization from the MAH (from the SRA country where the product is coming from, NOT the local MAH) to offer the product.
16	If regulatory approval is not in the country, or packs other than the locally-approved item can be imported, who is responsible to ensure the Regulatory Agency approval/ import permits are in place to import the medicine to target countries – UNICEF/PAHO, or the Company?	<p>Before placement of the Purchase Order, the LTA holder shall inform us if the product is not registered in the specific country.</p> <p>In your Proposal, please provide a list demonstrating in which countries the quoted products are registered, including any variations such as different pack size.</p> <p>Suppliers are encouraged to have their products registered in the countries where UNICEF/PAHO will support procurement and we encourage suppliers to indicate in their Proposal Submission where the products are registered with regards to the initial 6 countries. However, should the product not be registered in the country to be supplied, an import waiver will be requested from the recipient country and the LTA holder will be responsible for providing all the necessary information and documentation required to facilitate issuance of waiver to import the medicines into the respective country.</p> <p>We are in discussion with the first 6 countries on modalities to ensure early access in the pilot phase if product is not registered in recipient country.</p>
17	Is a translation required into local language, or is English language sufficient?	Please see above answer No. 10.
18	If documents are required during review (e.g. CoA, CPP, GMP), how much time we will be given to provide it?	CoA, CPP and GMP are needed in initial submission. However, CPP can be the most recent one for the product and CoA for the most recent batches of the product offered. For any additional document or clarification requested by us during review, the time for submission will be specified in the correspondence. Usually, it is a maximum of 7 days, but it might be longer if we understand that it is not realistic.

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19	please specify for which indication Hydroxycarbamide (item 120 and 130) is being used for?	Primary indication/s for all medicines in the tender will be according to WHO Essential Medicines List 2023. That does not exclude additional indications for which the medicine is registered. <a href="https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02">https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02</a>
20	Is it mandatory to complete below forms?  Annex 2i Letter of authorization permitting UNICEF and PAHO to access information submitted to the tender. Annex 2h Interagency finished pharmaceutical product questionnaire for BTPs and SBPs as we might not be able to complete or provide all the information required at this stage.	Yes, it is mandatory. If you do not have any of the annexes (for the product or site or other documents) upload a word document mentioning the specific reason for not having it e.g. Not applicable or Will submit the document latest (by XXXX date) etc. in lieu of the Annex. See Annex 3. Instructions for uploading technical documents to SharePoint. Annex 2i is mandatory.
21	Regarding the technical documents, it would be great if we can get to know the list of SRA countries. We had tried to open the link mentioned in Annexure 1 for WHO SRA list but it is showing an error.	Refer to <b>page 10</b> of the solicitation document, section 3.3. SRA refers to the following regulatory Authorities: <ol style="list-style-type: none"><li>1. European Union (including both The European Medicines Agency and National Competent Authorities)</li><li>2. Member of International Council on Harmonization of Technical requirements for Registration of Pharmaceuticals for human use as at October 2015 i.e. EU, US and Japan</li><li>3. The Three members of the European Economic Area – Iceland, Liechtenstein, and Norway</li><li>4. An ICH observer being a European free trade association and as represented by Swiss Medic (Switzerland), Health Canada (Canada)</li><li>5. Regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway and Liechtenstein</li></ol>
22	Please confirm if we are able to participate in this tender with some of the products without SRA registration or not.	Yes, you are able to participate in this tender with some of the products without SRA registration. Please see Non-SRA requirements, page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria and <b>slides 52 and 53 of webinar presentation.</b>
23	With reference to the said tender, considering SRA approval it is mentioned in the attached document on Pg,2	Please refer to the Annex 2f UNICEF Technical offer form (for SRA/WHO PQ products).

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	that we need Abbreviated questionnaire which is not available in the files shared on the UNGM portal.	Annex 2f is an abbreviated questionnaire for products with SRA MA. See also <b>slides 47 and 48 of the webinar presentation.</b>
24	Annual funding is \$5 billion while the procurement is increasing above \$ 7 billion so how this increased financial requirement is fulfilled by UNICEF?	<p>The \$7 billion is preliminary procurement figures for 2022 while the \$5 billion is average annual throughput. Refer UNICEF Supply Annual Report for 2022  <a href="https://www.unicef.org/supply/reports/supply-annual-report-2022">https://www.unicef.org/supply/reports/supply-annual-report-2022</a></p> <p>The annual funding of \$5 billion is the average annual value of funding for procurement through UNICEF while the \$7 billion is the projected procurement through put for 2022. UNICEF undertakes procurement on behalf of donors, governments and partners and the actual procurement value is determined by how much these donors, governments and partners procure through UNICEF.</p>
25	Can proposals be submitted only with some molecules, not with all the items that you request?	Yes, please see answer No. 6.
26	365 days from submission so LTA for 1 year will be valid from what date till what, accordingly price validity needs to be given, right?	<p>The LTA effective date is described in the LTA Terms and Conditions (Annex G: Section 2 – Effective Date; LTA-G).</p> <p>“The LTA-G will come into effect on the date UNICEF receives a copy of this LTA-G counter-signed by the Supplier and will be effective for a period (the “LTA-G Period”) beginning on [specified DATE] or the date UNICEF receives a copy of this LTA-G counter-signed by the Supplier whichever is later (the “Start Date”) and ending at midnight ([Copenhagen time]) on [specified DATE] (the “End Date”), unless earlier terminated in accordance with the provisions of this LTA-G”.</p> <p>The price validity of 365 indicated in the Solicitation document is for how long the prices offered in the proposal should be valid prior to LTA signing and allows for the technical and commercial evaluations to be concluded. before there could be any price adjustments by the bidders.</p>
27	What is the LTA validity?	It is 12 months from the effective date as described above in response to Question 26 with a possibility of extension for an additional 12 months.
28	Can you accept un-registered product?	No. Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria.

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29	Is the Marketing Authorization in country of supply mandatory?	It is preferred but not mandatory. We are in discussion with the first 6 countries on modalities to ensure early access in the pilot phase if product is not registered in recipient country. Refer to Response#14 and 28 above
30	If the Product is Tentatively approved with FDA?	Yes, please see page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. It is an approval under scientific opinion by SRA so it is acceptable.
31	Could products produced at SRA sites with a third party approved QA status can be approved and accepted by UNICEF/PAHO if UNICEF/PAHO have the QA/QC system of this party approved and recognized?	As long as the product has MA in the SRA country and is marketed in that SRA country, it is acceptable for us. You may need a declaration of equivalence if there are minor variations
32	is WHO PQ also mandatory? will it be indicated in the list? on which products must be WHO PQ and vice versa	The requirement is that the product is WHO Prequalified or has Marketing Authorization (MA) issued by SRA or approved under scientific opinions issued by SRA for high priority human medicines intended for markets outside their jurisdiction as per RFP Sub-section 3.3 and 3.4 under Section 3. Statement of Quality. You can search if product is WHO Prequalified here: <a href="https://extranet.who.int/pqweb/medicines/finished-pharmaceutical-products/prequalified">https://extranet.who.int/pqweb/medicines/finished-pharmaceutical-products/prequalified</a>  Note: Please notify us if you have made submission to WHO prequalification and/or SRA and product has been accepted by WHO PQ and/or SRA entity for assessment. If possible, provide timelines for when you expect to be listed by WHO PQ and/or SRA.
33	It will be a different purchase for each country?	Yes, it will be different purchase orders for each country.
34	Is it possible to give a proposal not for all countries?	If there are specific countries that you will not be supplying to, please mention this clearly in your submitted offer and kindly indicate reason(s).
35	Are the photos mandatory or can the arts of the products be sent?	Whether SRA or not - we request the artwork as a part of the Technical proposal. Photos of the product are used in lieu of the product samples and it might be required on a case by case basis.
36	Is 2E mandatory for SRA?	If the proposer is a manufacturer, we expect that this document is to be submitted, if not submitted, please indicate the reason for not submitting it-see Annex 3. Instructions for uploading technical documents to SharePoint - If you do not have any Annex (for product or site or other documents) to upload for any reason, please mention the specific reason for the same on a word /pdf file and upload the same in that

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		respective Annex upload. e.g. Not Applicable or Will submit the document later (by XXXX date) or Document cannot be provided or Not available or any other reason as applicable.
37	If one supplier bidder has registration in a country and another supplier does not, can the supplier without registration offer with the SRA label?	Yes. Please see page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria.
38	can supplier as well as wholesaler participate for same product-supplier combination?	In principle yes, however, the wholesaler is required to have an authorization document from the manufacturer stating that the wholesaler is allowed to provide an offer as well as sell the product in case of award. Please also refer to page 16 of the solicitation document regarding Section “10.2 Joint Venture, Consortium or Association”.
39	Knowing that the pilot phase should start in 2023, when is the tender outcome/ LTA award expected?	The timeline to complete evaluation of offers and issue LTAs depends on the number and complexity of offers. It is expected that evaluation should be completed by end of the year and a subsequently LTAs awarded to successful bidders as soon as possible.
40	please advise if we can offer a product which doesn't have SRA GMP at the moment	Yes, you can. Please submit your proposal in line with requirements <b>stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria.</b>  Note: Please notify us if you have made submission to WHO prequalification and/or SRA and product has been accepted by WHO PQ and/or SRA entity for assessment. If possible, provide timelines for when you expect to be listed by WHO PQ and/or SRA.
41	Is the product registered in any PAHO country acceptable	Yes, exceptionally, they can be accepted for supply through PAHO. PAHO recognizes products that have been approved by any of the Regional Reference National Regulatory Authorities for medicines, see the link: <a href="https://www3.paho.org/hq/index.php?option=com_content&amp;view=article&amp;id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&amp;Itemid=0&amp;lang=en#gsc&amp;gsc.tab=0">https://www3.paho.org/hq/index.php?option=com_content&amp;view=article&amp;id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&amp;Itemid=0&amp;lang=en#gsc&amp;gsc.tab=0</a>



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42	Data matrix codes for products for Uzbekistan required?	This will be addressed as part of customization required for specific countries at the time of placing the actual PO . However bidders should indicate, in their proposal submissions if they already have products registered in Uzbekistan with data matrix codes.
43	Will UNICEF/PAHO share the overview list of awarded bids after evaluation?	UNICEF publishes all contract awards online - on the following link <a href="https://www.unicef.org/supply/contract-awards">https://www.unicef.org/supply/contract-awards</a> which is also included in the list of useful links in the Presentation.
44	Can we share all oncology SRA products available with respective company or restrict to asked list?	For this tender, please restrict the offers only for the products listed in the Product List Annex C and Amendment No.1 of the Solicitation Document. Alternative pack sizes Take note that alternative pack types of the same medicine can be included, Refer to response to Query#5 above.
45	How will the possibility of consolidation of products be considered in the evaluation of the tender? Is there a preference to provide as many products as possible from one consolidation point?	This will be one of the elements to be considered in the commercial evaluation of the proposal but will not be a limiting factor in the award process.
46	Is there one LTA per supplier, per item?	LTAs are awarded in accordance with the Solicitation Method used. Suppliers are likely to be awarded one LTA for this solicitation method for single or multiple products. A Supplier may be awarded one LTA for multiple products . LTAs maybe awarded to multiple suppliers for the same product. Please see Section15.6.5 Multiple Long Term Arrangements LTA-G(s);, page 23 of the RFP document.
47	If the PAHO is going to have a separate technical evaluation for the products which are not SRA approved but are eligible as per PAHO criteria of regional NRA's?	There is only one technical evaluation. The PAHO NRA criteria is a part of the evaluation
48	Can CoC be provided when COA is not available?	No. Certificates of Analysis (FPP CoA) must be submitted with the offer and will accompany products when they are delivered to UNICEF or designated UNICEF consignees.
49	For wholesalers, is the expectation that every manufacturer that wholesalers bid will fill annex 2i or is it for the wholesaler as the bidder itself to fill?	Wholesalers need to fill Annex 2i because they are making an offer and sharing the information with UNICEF and PAHO.
50	Is there a green light period from supply country? how to factor in the lead time if we have to provide FCA lead time	There might be greenlight requirement for some of the countries where the products will be shipped however this should not affect the lead time indicated in the Proposals. The lead time

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		indicated in the proposal should reflect the time it takes for the Proposer to have the goods ready for shipment from the time an order is received (i.e. production time and delivery to named port).
51	Can we make offer only for one specific country ?	Yes, this can be acceptable, but it has to be clearly specified in the offer.
52	What percentage of the child population is covered per country with this tender?	<p>We don't have the actual % of the child population that will be reached through The Global Platform for Access to Childhood Cancer Medicines . However the Platform aims to reach 50,000 children per year by 2027 approximately representing</p> <ul style="list-style-type: none"> <li>• 25% of all children with cancer in the world</li> <li>• 30% of children with cancer in low and middle-high income countries</li> <li>• 60% to 70% of children with cancer in low and lower-middle income countries</li> </ul> <p>By 2027, the Global Platform will have provided medications for more than 120,000 children (Refer to Slide 10 in the Presentation)</p>
53	Pls clarify, if our product is registered in the NRA country, specified in National Regulatory Systems with the exception of SRA would we still be considered eligible to participate in the bid.	Yes, Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. Please refer to slides <b>52, 53</b> in the Webinar presentation.
54	In most of the products we are not registered in SRA but we are registered in Latin countries can we provide offer for these products?	Yes. Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria
55	The products which are filed with EU should be categorized in SRA or non SRA ?	If by EU, you mean EMA central procedure, then yes, it is classified as SRA. Please see page 10 of the Solicitation document, subsection 3.3. for list of SRA countries and also <b>refer to response to question 23 above on list of SRAs.</b>
56	The pds are under evaluation and MA not received yet. Please clarify, if our product is registered in the NRA country, specified in National Regulatory Systems with the exception of SRA would we still be considered eligible to participate in the bid.	<p>Yes, please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. Please refer to slides <b>52, 53</b> in the Webinar presentation. See answer No. 53.</p> <p>Note: Please notify us if you have made submission to WHO prequalification and/or SRA and product has been accepted by WHO PQ and/or SRA entity for assessment. If possible, provide timelines for when you expect to be listed by WHO PQ and/or SRA.</p>

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57	Clarify FCA, per definition: "...seller is required to drop off the shipment to a named destination or seller's premise..."; is there a specific named destination for UNICEF and PAHO, or will product be picked up from seller's premise?	By definition the FCA Incoterms (2020) means the seller is only responsible to the named place (for this tender it is named airport/seaport). Supplier is responsible for loading. Risk and cost are transferred to the buyer as soon as goods are delivered at the named place. Unloading is the buyers responsibility. As such the product will therefore not be picked up from the Seller's premises but seller must deliver to a named airport/seaport. The Seller shall identify a suitable airport/seaport where to deliver the goods and from where risk and cost will be transferred to UNICEF/PAHO freight forwarders. The FCA price quoted in the offer should therefore reflect this accordingly.
58	If the product is approved in the recipient country, do we need to supply the product/pack approved by that country Regulatory Agency or can we supply product from a SRA, for example US?	Kindly offer both products as two separate lines. See answer No. 11.
59	Can we offer other incoterms like CIP?	No, only FCA terms should be offered for this tender. Offering other incoterms will complicate the commercial evaluation process
60	Can wholesaler offer same product from multiple sources by adding a row in price form annex D?	Yes, but submit Annex 2f, 2g and 2i for each product (manufactured by a different manufacturer – from a different source). Also if the prices are different then these should be indicated in separate lines in the Commercial Offer (Annex D) . See response to number 5 above
61	is incoterms FCA country wise or to UNICEF HQ?	The Incoterm is FCA (named Seaport/airport). Please see answer to No.2 and 57 above.
62	Does the CPP need to be issue by the SRA the company chooses? Or is there flexibility.	It should be issued by the same SRA which registered the product/issued MA.
63	If any label/CMC changes on products supplied during the 1 year agreement, will the company need to inform UNICEF?	Yes, please see Annex 1. Technical requirements and page 22 of the tender document, under Section 15.5. Special Technical Instructions - sub section 15.5.1
64	In order to prepare for future countries, will the list of next 6 countries/ longer 50 country list be issued in advance of the next expected tender bid round? It seems from the questions that this clarity would be very helpful.	There will be no separate tender bid round for the next list of countries. The results from this tender will be used to supply the medicines to any additional countries. The Purchase orders issued against the LTAs to be established from this tender will indicate the final country of destination for each order.
65	Will the offer for unregistered products be accepted?	No. If the product is not registered in any country in the world, an offer will not be accepted. Refer to Response to #28

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		Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. Please refer to <b>slides 52, 53</b> in the Webinar presentation. See answer No. 53.
66	SRA approved products form two manufacturing plants, is it acceptable from the two plants? Zone 4 stability from one plant and Zone 2 from another plant, is it possible to offer from both sites? Requirement of CPP , that needs to be from the Country of Origin?	Yes, you can offer products from two plants but as 2 different offers (one set of documents for each product). In some cases of bidders that are manufacturers, one offer of the product from two manufacturing sites might be acceptable. Yes, you can offer from both sites but again as 2 different offers (one set of documents for each product) CPP needs to be from the country of origin or from the country where a product is registered, released and marketed. During the evaluation, sample CPP for the specific product is needed but specific CPP will be needed for the shipment. Please indicate that you are submitting a product that will be coming from two different sites when you ask for creation of the “Technical Folder”.
67	Eligibility of lead time how is it?	The lead time is the time it takes from the time an order is received to when the goods are ready for delivery to the named airport/seaport (See Response to #50 above). The eligibility of lead time in the award process will consider whether the lead time offered is long or short in comparison to other offers received for the same product.
68	If the product is under assessment with SRA country, should we give the documentation as SRA or non-SRA?	Your offer for SRA and Non SRA product should be made as two different offers ( 2 separate lines in the offer document) Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. Please refer to slides <b>52, 53</b> in the Webinar presentation. <b>See answer No. 53.</b>  Note: Please notify us if you have made submission to WHO prequalification and/or SRA and product has been accepted by WHO PQ and/or SRA entity for assessment. If possible, provide timelines for when you expect to be listed by WHO PQ and/or SRA
69	You prefer in SRA language country or in English?	We prefer English, but SRA authorities could be in countries with different languages. When it is translated to English, we expect declaration of equivalence. <b>See slide 41 of the webinar presentation.</b>

No.	Bidder(s) Query	UNICEF Response
70	Shelf life required for the products upon its arrival to destination.	Please refer to Section 22. SHELF LIFE AND WARRANTY, page 27 of the tender document. It is expected that the remaining shelf life will be as long as possible at the time of arrival in the country of destination. However there might be exceptions to this depending on the urgency of the need for the product and the exceptions will be treated on a case-by-case basis.
71	Regarding Annex 2a. If a company is responsible for labelling/secondary packaging as well as batch release of the final product and thus is named as MAH and manufacturer in the Patient Information Leaflet. Is it sufficient if the company answer Annex 2a in its name or is it needed to hand in Annex2a for the API and bulk manufacturers?	A company should list all manufacturing sites and submit annex 2a for all manufacturing sites included in the manufacturing processes of the finished pharmaceutical product/s (different manufacturing steps). It is not needed for API manufacturers.
72	We observe that Annex 2c and Annex 2h are same only versions are different, could please let us know which Annex we have to fill out and submit.	Annex 2h is for biological products and biosimilars and Annex 2c is for all other medicines.
73	Will dispatch of the products listed in tender document to be in 1 lot or multiple lot.	Dispatch of the products will be based on the list of products in the purchase orders and whether they are required to arrive in country of destination at the same time or not. If the products are required to arrive in country at the same time (i.e. bundled), it will be clearly indicated in the purchase order.
74	In few products our company's registration status spans PICs and various other countries, excluding SRA or NRA and we are optimistic about the potential of our submission and believe that we can provide valuable contributions to the project hope this not lead to disqualification of our submission. Kindly advise.	Yes, Please submit your proposal in line with requirements stated on page 22, under 15.3 TECHNICAL AND QUALITY CRITERIA – Sub Section 15.3.1 Mandatory Criteria. Please refer to slides 52,53 in the Webinar presentation. See answer No. 53.
75	Could UNICEF please confirm whether the local regulatory agency will accept an SRA approval for a medicine, even if there is a local regulatory approval for that medicine, or whether ONLY a local regulatory-approved presentation will be possible?	The SRA requirement at this stage is for product assessment. We are in discussion with the first 6 countries on modalities to ensure early access in the pilot phase if product is not registered in recipient country.  See response to Question 16.