

Pre-bid Webinar for RFP-DAN-2024-503720 the Supplementary Tender for Paediatric and Adolescent Cancer Medicines

Questions and Clarifications

Date of Issuance: 12-08-2024

Question 1. Is the previous Oncology tender from 2023 evaluated or is it still under evaluation.

Clarification: Evaluation of previous Oncology tender (RFP-DAN-2023-503604) is almost finalized. To note that there are a few offers, for which clarifications are yet to be finalized.

Question 2. If our company has participated in the Oncology tender in 2023, then we should not be tendering again in 2024?

Clarification: If you submitted the proposal for certain products in 2023, then you shall not be tendering for the same products in 2024 unless:

- new product/-s, in accordance to the product list (Annex C) became available in your company's portfolio.
- product/-s you tendered for in 2023 became available in different pack size and/or strength; FPP and/or manufacturing site has changed, or any other changes that have been encountered since 2023.

Question 3. Is it the case that separate RFQ will be required to be filled with fresh price by the awardee. Why is this? Why can't the initially tendered price be workable for all purposes till the tenure of this tender?

Clarification: The initially tendered price applies, e.g. if the proposal is submitted within Window 1 deadline, then re-tendering for the same product/-s in Window 2, 3 or 4 is not required.

Question 4. Could the rationale for these submission deadlines be explained please? And how do they pertain to the finalization of LTAs?

Clarification. We aim at building a complete and comprehensive cancer medicines portfolio therefore we have made provision for four expand submission windows. At closure of each window, evaluation will be undertaken, and LTA establishment will be linked to the evaluation outcome of each window.

Question 5. Can we submit the bid in any of the mentioned Windows?

Clarification. Yes, proposals can be submitted in any window from 1 to 4.

Question 6. If a window opens on 13th August, when this window closes? There are 4 windows for each deadline. What is the significance of each deadline? Will the window be open for only 24 hours of the specified date?

Clarification. There are 4 proposal submission Windows with following time frames:

Window 1: from 12th July (tender launch date) to 13th August 2024, 23:59 hrs Copenhagen time;

Window 2: from 14th August to 2nd September 2024, 23:59 hrs Copenhagen time;

Window 3: from 3rd September to 4th November 2024, 23:59 hrs Copenhagen time;

Window 4: from 5th November to 3rd February 2025, 23:59 hrs Copenhagen time.

The four Windows allow for proposal submission within any of the four mentioned deadlines. The first deadline for submission is on 13th August 2024. If you are not ready to submit your commercial and technical offer on that date, you have an opportunity to consider subsequent windows.

Question 7. Can we modify uploaded documents if required; provided that the deadline is not missed?

Clarification. Yes, uploaded documents can be modified by mentioning the document title "xxxxx - Amendment", provided modification is taking place prior to respective window submission closing date.

Question 8. Do we have to participate again if we have participated already in the last year oncology of UNICEF PAHO?

Clarification. If you have already participated in the first tender in 2023, then you do not need to offer same product in 2024 unless you will be offering a new dosage or pack size, a new manufacturing site for products included in the tender product list.

Question 9. We have participated in this last year and we are getting RFQs also so there is no need to participate in this tender?

Clarification. Please see provided Clarifications under questions 2, and 8.

Question 10. There are two parts to tender: commercial and technical. Can we request for Sharepoint access when the commercial proposal is partially submitted?

Clarification. You may consider requesting for the link to Sharepoint folder to upload the technical proposal provided that your commercial proposal will be **fully submitted** within the same submission Window as the technical proposal.

Question 11: The validity mentioned is 365 days. as there are 4 deadlines can you please advise according to which submission date should we have the quote valid?

Clarification. The proposal validity of 365 days starts from the Window submission deadline date you submitted your proposal to. UNICEF may request the Proposer to extend the validity period. To decline the extension request will result to disqualification of the proposal.

Question 12. How many LTAs will be signed for one product?

Clarification. We aim at having a sufficient number of LTAs to meet the current and future demand, which may vary from product to product.

Question 13. Does it mean that bids submitted in the first submission window would have higher chances of success, compared to the submissions in the last window, as long as they meet the criteria?

Clarification. You are welcome to submit your proposal in any of the submission windows. Due to urgent demand, we encourage suppliers to make submissions in the first windows or communicate their intent to participate in subsequent windows. All bids received will be evaluated in line with the public procurement principles shared. ***“please refer to Power Point presentation RFP-DAN-2024-503720 Webinar PDF Presentation”.***

Question 14. Will orders be collated and created 'in bulk' (even though destinations are separate)? Or small requests, ad-hoc, country by country?

Clarification. There will be purchase orders for specific quantities and destination countries, consolidated orders may be considered to the best extent possible in line with Country timelines.

Question 15. Can you share the list of countries that would have demand for the requested Oncology products and the tentative forecast for the same?

Clarification. The list of initial countries with overall estimates is included in the presentation.

The presentation is uploaded on UNGM platform, with reference ***please refer to Power Point presentation RFP-DAN-2024-503720 Webinar PDF Presentation”.***

Question 16. If the dosage form is different from the tendered product list, could we bid the dosage form we have?

Clarification. There is a tendered product list as Annex C available. If there are any product/-s that are different from the description of the listed products these products are to be added as alternatives.

Due to the existence of several strengths for some products suppliers are encouraged to offer alternative products where applicable. When offering alternative product/-s, please add an extra row in the commercial offer template_Annex D, e.g.

Item No.	Route of Administration	Product Short description	Indicative pack size and type (Other pack sizes/types will be considered)	Item No.	Description of Product Offered	Strength Offered	Dosage Form Offered	Pack size Offered (total No. of Units in One Pack)	Shelf-Life (in months only)
10	Oral	Ca folinate 5mg tabs	Blister pack of 28	10					
10.1	Oral	Ca folinate 5mg tabs	Blister pack of 10						
20	Oral	Ca folinate 15mg tabs	Bottle of 10	20					

Question 17. We would like to participate in this tender directly as well as through our partners. Can we participate via multiple Bidders. Please confirm.

Clarification. If the Proposer is a group of legal entities that will form or have formed a joint venture, consortium or association at the time of the submission of the Proposal, only the designated lead entity will enter into the LTA-G with UNICEF or PAHO. For more details, please refer to point 10.2 of the solicitation document.

Question 18. Please advise about the below section that is required to be submitted under technical requirements submission:

- 1)2c Interagency finished pharmaceutical product questionnaire.
- 2) 2d IAFPPQ Commitment and authorization - Section 5.
- 3)2e API declaration Form.

Clarification. The tender is primarily for SRA registered products. The following annexes are required i.e. Annexes 2a (manufacturer)/2b (wholesaler), 2f, 2g and 2i. Additional if applicable 2j or 2k. For Non-SRA site release you may be required to submit documentation to justify the differences as per documentation under NON SRA products (please refer to annex 2c).

Therefore, annexes 2d and 2e are not necessary for this tender. Annex 2c (may not be applicable for most cases including Non-SRA site release) but maybe applicable to the extent of annexes embedded in it in order to justify some differences for NON-SRA site release e.g. differences in pack type.

Question 19. If the products come from external supply organization, how accurate the annex 2a should be?

Clarification. Annex 2a is for suppliers/bidders who are manufacturers. In case of contract manufacturers Annex 2a would be applicable. If you are not the manufacturer, then you would need to fill in Annex 2b (for Wholesalers).

Question 20. Can we participate with SRA product or also with NRA registered products

Clarification. Only SRA, WLA or WHO PQ approved. For more details, please do refer to 3.3 and 3.4, page 10 and 11 of the solicitation document.

Question 21. Would you award one manufacturer or multiple manufacturers for a single molecule. If multiple, how would you distribute the quantities amongst multiple awardees?

Clarification. Several bidders maybe successful to get LTA (Long Term Agreements) for the same molecule. The awarding of supply is through issuance of a Purchase order (PO). PO award considers certain factors, such as the amount of requested quantities, among other factors as applicable.

Question 22. Will you accept only WHO accreditation manufacturers?

Clarification. No. The criteria is WHO PQ, SRA or WLA approved products.

Question 23. If COP is not available for all countries, at present, can we submit it later?

Clarification. Yes.

Question 24. Samples are required for the tender: shall we submit the samples only to UNICEF?

Clarification. Samples should only be provided upon request from UNICEF, but please upload closeup pictures of the products along with other technical documents. For further details please refer to point 7.7 of the solicitation document.

Question 25. Is the batch release of the products from SRA compulsory? as it will increase the expenses and affect the quotation?

Clarification. No. Non-SRA batch release is acceptable. You will need to fill in and sign Annex 2j (Declaration of Similarity).

Question 26. We have products available in USP/EP/ BP grade/ EP grade with batch release. Can we share our quotation in ladder form?

Clarification. So long as the primary criteria that the product is approved by SRA, WLA or WHO PQ, then the different grades would be considered as separate offers. Therefore, you would need to fill in annexes 2f and 2g per grade.

Question 27. Is a 'Product' considered a particular medicine, or is every different pack size considered a product? They are indicated separately on slide 38 (i.e a product is a product and a pack size is an alternative presentation of a product)?



Clarification. A product is FPP in its final commercial pack. We have specified the pack sizes to be offered. However, you can offer the pack sizes you have. If you are offering more than one pack size, each pack size is considered a different offer.

Question 28. Is there any chance if I participate with Non SRA/ Non Latin Registered Product, but on the basis of my very competitive price, can my bid be accepted.

Clarification. The criteria is WHO PQ, SRA or WLA approved products. For more details, please do refer to 3.3 and 3.4 page 10 and 11 of the tender document.