

UNITAID-CHAI ARV Supplier Selection Process
Supplier Q&A –November 9, 2010

Below are several questions that UNITAID/CHAI has received regarding the recently ARV supplier selection process, together with CHAI's responses.

1. *Can you please clarify what information should be provided under Section 5 (Required Information for Responses) requirement 1, relating to technical specifications of the product?*

For each product being proposed, the supplier is requested to provide the specifications used to test and release the product. This can be a published monograph (i.e. USP or WHO), or it can be the supplier's own internal specifications. Where internal specifications are used, the supplier must provide the specifications with their response.

2. *Can you confirm that no additional documentation is required for products that have already been approved by a stringent regulatory authority¹?*

Suppliers are requested to provide the regulatory status for all products being proposed. No supporting documentation is required for products that have been approved by a stringent regulatory authority, unless the product is newly approved and has not yet been updated on the regulator in question's website or can otherwise not be verified. In this case, CHAI/UNITAID will request confirmation of approval in the form of an official letter from the stringent regulatory authority.

3. *A copy of the regulatory dossier has been requested for each product that has been submitted but not yet approved by a stringent regulatory authority. CHAI/UNITAID not being a regulatory body, we do not want to submit the dossier for review due to confidentiality concerns.*

Copy of the dossier is required for making a complete technical assessment of the product yet to be approved by a stringent regulatory authority. The information so provided is kept completely confidential and cannot be used for any purpose other than reviewing the product for participation in the program.

4. *Please confirm that the entire dossier must be provided. If so, will electronic/ CD ROM copies be accepted, or are paper copies required?*

A copy of the entire dossier is to be provided. Electronic copies are acceptable.

5. *For products submitted but not yet approved by a stringent regulatory authority, does the full BE report need to be submitted along with the dossier copy, or will a summary BE report suffice?*

A summary BE report is acceptable; however, suppliers must be willing to provide the full BE report upon request by CHAI/UNITAID.

¹ Stringent regulatory authority is defined as per the International Conference on Harmonization. See www.ich.org for list of participating ICH members.

6. *For products submitted but not yet approved by a stringent regulatory authority, do complete details of the DMF need to be provided?*

Yes.

7. *Can one DMF copy per molecule be submitted for reference (i.e one copy for both single and fixed-dose combination products)?*

Yes.

8. *Please confirm the eligibility status of products that are still in the R&D phase or for which a regulatory dossier is in the process of being compiled, but has not yet been submitted to a stringent regulatory authority.*

In order to be considered eligible, products without stringent regulatory approval must have been submitted for such approval by November 12, 2010 for purposes of primary supplier selection and by January 28, 2011 in the case of secondary supplier selection. If a particular product is neither approved nor submitted by any supplier, CHAI/UNITAID reserve the right to conduct direct negotiations as soon as the first submission is made, or to hold a separate selection process once two or more suppliers are eligible

9. *We are close to getting an SRA approval for our product, but are not eligible to participate for this product since there are already more than two SRA approved sources for the product. If we submit a proposal, will we be included in the list of pool suppliers once we get approval?*

Under the current terms of the program, the approval for such products must be received by November 12, 2010 for primary supplier selection and by January 28, 2011 in the case of secondary supplier selection. Any product getting approved after such date will not be eligible for participation.

10. *We understand that CHAI sets ceiling prices for certain ARVs under its Procurement Consortium price agreements. Will these ceiling prices be announced before suppliers are required to quote for the UNITAID Pediatric and Second-Line projects?*

Ceiling prices will be set by CHAI for use by its Procurement Consortium after all responses to this RfP have been received. The process for setting ceiling prices is independent of the process for selecting suppliers to the UNITAID Pediatric and Second-Line projects.

11. *Do you have details of registration cost in each of the countries specified in Schedule 1 and 2?*

No, CHAI/UNITAID do not have information pertaining to registration costs in each of these countries. Suppliers are encouraged to access this information through their in-country regulatory agents.

12. *The supplement on supplier selection criteria talks about inclusion of a “registration score” based on in-country registrations and submission of applications for such registration. For the purpose of inclusion in this score, what constitutes a “complete” submission?*

An application is deemed “complete” and is eligible for consideration under the “registration score” parameter if

- The complete dossier and the supplementary data asked for by the country regulations have been submitted;
- The applicant has been granted an application number by the NDRA; and
- The fee stipulated by the NDRA for registration has been paid.

13. *We were awarded the primary/ secondary supplier status for our product during the last year's tender. However, we have not received many orders for our product during the year. What is happening?*

As reflected in the RFP, actual order quantities from a supplier are dependent on many factors, including in-country registration status and local regulations governing the use of the product. If the number of registrations for the product is small, it will have an impact on amount of actual orders placed for that product.

14. *When submitting an Expression of Interest may we quote prices in Euros?*

As reflected in the RfP, all prices should be quoted FCA Airport and it is preferred, but not mandatory, that prices be indicated in U.S. dollars. If quoted in a currency other than US dollars, prices must be accompanied by the exchange rate used.

15. *Are prices from the the RfP process going to be published on UNITAID's website as has been the practice in previous years?*

Yes.

16. *CHAI has requested we provide the "production batch size" as part of our Express of Interest. We have different batch size options for our products, what information do you require?*

Please provide us with the minimum production batch size for each of the products that you propose to supply. This information will aid us in allocating order volumes after supplier selection has occurred.

17. *Our pack size for certain products is different than what is indicated in the RfP. Are we eligible to bid?*

Yes, bids for the same product but different pack size are eligible to bid. Please indicate the pack size that you propose to supply in your Expression of Interest and we will adjust prices across bids accordingly.

18. *The RfP lists both plain and dispersible formulations for Abacavir 60mg and Zidovudine/Lamivudine 60/30mg separately. May we conclude that the plain formulation for Abacavir 60mg and Zidovudine/Lamivudine 60/30mg refers to scored tablets?*

No, Abacavir 60mg and Zidovudine/Lamivudine 60/30mg "plain" formulations does not necessarily refer to scored tablets. For all "plain" formulations you may propose to supply a plain or scored tablet.

All bids for 'Efavirenz 200mg – scored' on the other hand must be for the scored tablet formulation only. Similarly, proposals to supply dispersible formulations must be for an appropriate dispersible product only.

19. *Do you require scored or dispersible tablets for the following formulations: Zidovudine 100mg, Zidovudine/Lamivudine/Nevirapine 60/30/50mg, Abacavir/Lamivudine 60/30mg, Stavudine/Lamivudine 6/30mg, Stavudine/Lamivudine 12/60mg,*

Proposals to supply plain or scored tablets for the above formulations are both acceptable. In cases where a scored or dispersible formulation of a product is required, it has been specified in the RfP.