

UNITAID-CHAI ARV 2010 Supplier Selection Process

Supplier Q&A

November 9, 2009

Below are several questions that 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 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.*

A 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 provided to CHAI will be kept completely confidential and will not be used for any purpose other than for reviewing the product for participation in the projects.

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 required to be provided. Electronic copies are acceptable.

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

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

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

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 13, 2009. 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 project, the approval for such products must be received by November 13, 2009. Any product receiving approval 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. *In the cost-plus models provided, what % profit margin is accepted?*

CHAI works collaboratively with cost-plus manufacturers to determine a modest but sustainable profit margin. The profit margin varies from product to product and there is no fixed percentage that is used across product categories. For high-volume, commoditized products, such as first-line ARVs, profit margins tend to be lower (typically below 10%), while those for second-line ARVs are higher.

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

No, CHAI 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.

13. 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.

14. 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 (or the ability to obtain waivers) and local regulations governing the use of the product. If the number of registrations/ waivers for the product is small, it will have an impact on amount of actual orders placed for that product.

15. Can you clarify the participation of Haiti and South Africa in the program and whether their volumes have been reflected in the forecasts?

The participation of Haiti and South Africa are being explored by CHAI and UNITAID. As such, the volumes for these two countries have not been included in the forecasts in the supplier letter, and suppliers should not assume their inclusion as they prepare their bids.