

UNITAID-CHAI OI Supplier Selection Process
Supplier Q&A – March 7, 2011

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

1. *Can you please define the format for the Interagency Pharmaceutical Product Questionnaire?*

Please find a copy of the Interagency Pharmaceutical Product Questionnaire with this mail. The conditions under which one must provide this questionnaire are as follows (*ref. Schedule 5, Pg 27 of the OI RfP sent on February 22, 2011*):

- a. In the case of single or limited-source pharmaceuticals, (a) the drugs must be either prequalified by WHO or approved by a stringent regulatory authority **by March 15, 2011** or (b) in case there is only one or no equivalent product that meets this condition, in such event: (i) a completed Interagency Pharmaceutical Product Questionnaire must be submitted no later than **March 15, 2011** and the product must be manufactured at a site that is compliant with WHO or stringent regulatory authority standards of cGMP₂, provided that the Ministry of Health of the beneficiary country concurs that the products may be supplied on the basis of the conditions set out in (b)”

2. *Can you please clarify whether samples have to be sent in with the Interagency Pharmaceutical Product Questionnaire?*

No, you do not need to send in samples of the product with the Interagency Pharmaceutical Product Questionnaire. In lieu of samples of the product, what we would need are as follows:

- a. Photographs of the product (photographs should clearly show the tablets/ capsules; in case of syrups/powders, photographs of the product in the bottle/vial)
- b. Photographs of the packaging and labels (clearly showing the smallest text written on it)
- c. Photographs of the inserts (if any) that will be in the final product pack
- d. Pricing, Technical and Other information for these products has to be submitted as for other products as detailed in the RfP.

3. *Another company has recently acquired our company. Therefore, the name of the entity handling the products mentioned in the RfP has changed. Given that the RfP has been addressed to us under a different entity name, can you please confirm whether we can respond to the RfP with products under the name of the new entity?*

Yes, you may respond to the RfP with your bids for products under the new name. However, all remaining requirements, especially for quality standards of products being supplied must be satisfied. Please refer to Schedule 2 and Schedule 5 in the RfP that was sent to you for further details on the requirements for OI drugs under the UNITAID project.

4. *Can we respond to the RfP with products that are manufactured by our Third Party manufacturers and Loan Licensee vendors?*

Yes, you may respond to the RfP with your bids for products that have been manufactured by your third party manufacturers and Loan Licensee vendors. However, all remaining

requirements, especially for quality standards of products being supplied must be satisfied. Please refer to Schedule 2 (Section B) and Schedule 5 in the RfP that was sent to you for further details on the requirements for OI drugs under the UNITAID project.