



A NEW  
PERSPECTIVE  
ON TB DRUG  
PROCUREMENT.

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**BACKGROUND PAPER: COORDINATING BOARD MEETING 24-25 APRIL 2006**

**SUBJECT: STB Partnership promotion of the WHO TB Prequalification Project and a provisional process to assist in the assessment of quality of products yet to obtain prequalification**

## **Introduction**

### *Background*

For the first line treatment of TB The Global Drug Facility (GDF) currently provides access to 5 different drugs in 14 different forms with plans to expand the catalogue to include paediatric and second line treatments.

There are currently no suppliers with prequalified products under the WHO TB Prequalification Project which could supply all 5 drugs in all 14 forms.

GDF fully supports the WHO TB Prequalification Project but remains unable to restrict its procurement to only products prequalified under the WHO TB Prequalification Project.

GDF currently holds contracts for supply of anti-TB drugs with companies which do not have prequalified products.

The need to award contracts to non prequalified products has resulted in the implementation of an ad hoc process for assessment of the quality of the products submitted under the GDF Limited International Competitive Bidding (LICB) processes.

Specifically there are no prequalified brands under the WHO TB Prequalification Project for:

- Streptomycin;
- Rifampicin / Isoniazid / Ethambutol;
- Rifampicin / Isoniazid 150/150 mg;
- Water for Injection;
- Any of the proposed paediatric formulations which are to be added to the catalogue.
- Any of the second line treatment options for which the GDF is currently conducting procurement.

There is one prequalified brand under the WHO TB Prequalification Project for:

- Ethambutol (Cadila);
- Pyrazinamide (Cadila).

There are two prequalified brands under the WHO TB Prequalification Project for:

- Rifampicin / Isoniazid 150/75 mg (Lupin and Sandoz [Strides]).

There are three prequalified brands under the WHO TB Prequalification Project for:

- Rifampicin / Isoniazid / Pyrazinamide / Ethambutol (Wyeth<sup>1</sup>, Sandoz [Strides] and Lupin).

GDF considers for there to be adequate competition in these markets and for the suppliers to respond appropriately to the needs of the market, the GDF should actively seek to have at least 3 prequalified suppliers under the WHO TB Prequalification Project for each product line. GDF would maintain its current policy of awarding to more than one supplier (wherever possible) for each product line.

It is of note that prequalification is but one of the criteria that would be used to assess the ability of any supplier to be involved in an LICB, another very important factor being the

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<sup>1</sup> Wyeth have a prequalified product but have not submit ted into the GDF LICB process in the past despite being invited.

ability/willingness of that supplier to supply the product in a timely manner when requested to do so. In this way GDF considers that a supplier is considered to meet this criterion if it would be able to supply within 90 days of such a request. It is therefore noted that throughout this paper when GDF refers to a prequalified supplier this implies not only prequalification but also the ability to supply the product within 90 days of request.

GDF considers there are a number of mitigating factors which have resulted in the current situation of little to no prequalified competition being available for submission into its LICB processes these include, but are not limited to, the following factors:

- The process for prequalification under the WHO TB Prequalification Project is, appropriately, very stringent. However, considerable feedback has been provided to GDF and PREQUALIFICATION from suppliers that it is:
  - difficult to provide all the information when the terms of reference for the evaluation, change after submission of the dossier;
  - that requirements for the WHO TB Prequalification Project differ considerably to those required for a number of other world class regulatory agency assessments including the FDA and European evaluators, which makes re-working the data to meet these criteria time consuming;
  - there is a perceived lack of transparency within the process of evaluation which makes it difficult for the suppliers or for that matter the GDF, to assess the stage at which a product may be through the evaluation process;
  - unlike other regulatory agencies there are no agreed response timelines proposed for the WHO TB Prequalification Process.
- GDF does not consider that the suppliers are without fault and that there has been a level of reticence to submit their dossiers into both the WHO TB Prequalification Project and other countries' regulatory authorities.

#### *Proposed Provisional Process*

In order to allow GDF to supply products to Grant and Direct Procurement customers it has been essential for it to establish a process for quality assessment outside of the WHO TB Prequalification Project framework. A number of processes have been proposed for this purpose including The Global Fund process.

Having considered the currently available processes GDF consider that it should approach the Prequalification team with a revised version of its current provisional assessment requirements, which would provide more information to GDF for it to be able to make an informed, evidence and risk-based assessment of quality. GDF would also request from the Prequalification team, feedback on whether these assessments should or could be conducted in a timely manner by the team or whether these assessments should be outsourced. Should it be decided between the GDF and the Prequalification team that outsourcing this activity would be the most efficient and cost effective mechanism then GDF propose to seek quotations from companies and groups known to it to have the experience and expertise to conduct such evaluations prior to awarding a contract.

#### *Promoting the WHO TB Prequalification Project*

GDF proposes to continue to promote the WHO TB Prequalification Project to suppliers. In addition to its usual activities including actively motivating suppliers to submit quality dossiers for evaluation under the WHO TB Prequalification Project, GDF propose to give a financial advantage to suppliers which have obtained prequalification for their products.

This would be achieved by assessing a prequalified supplier's price, submitted during an LICB process, on the basis that it may be higher than those submitted by non prequalified suppliers and allowing a buffer between the price of the prequalified supplier and the non prequalified suppliers. The number of prequalified suppliers submitting into the LICB process for any given product would determine the price buffer allocated for prequalified suppliers during the evaluation process.

To illustrate how this would work the following example is provided:

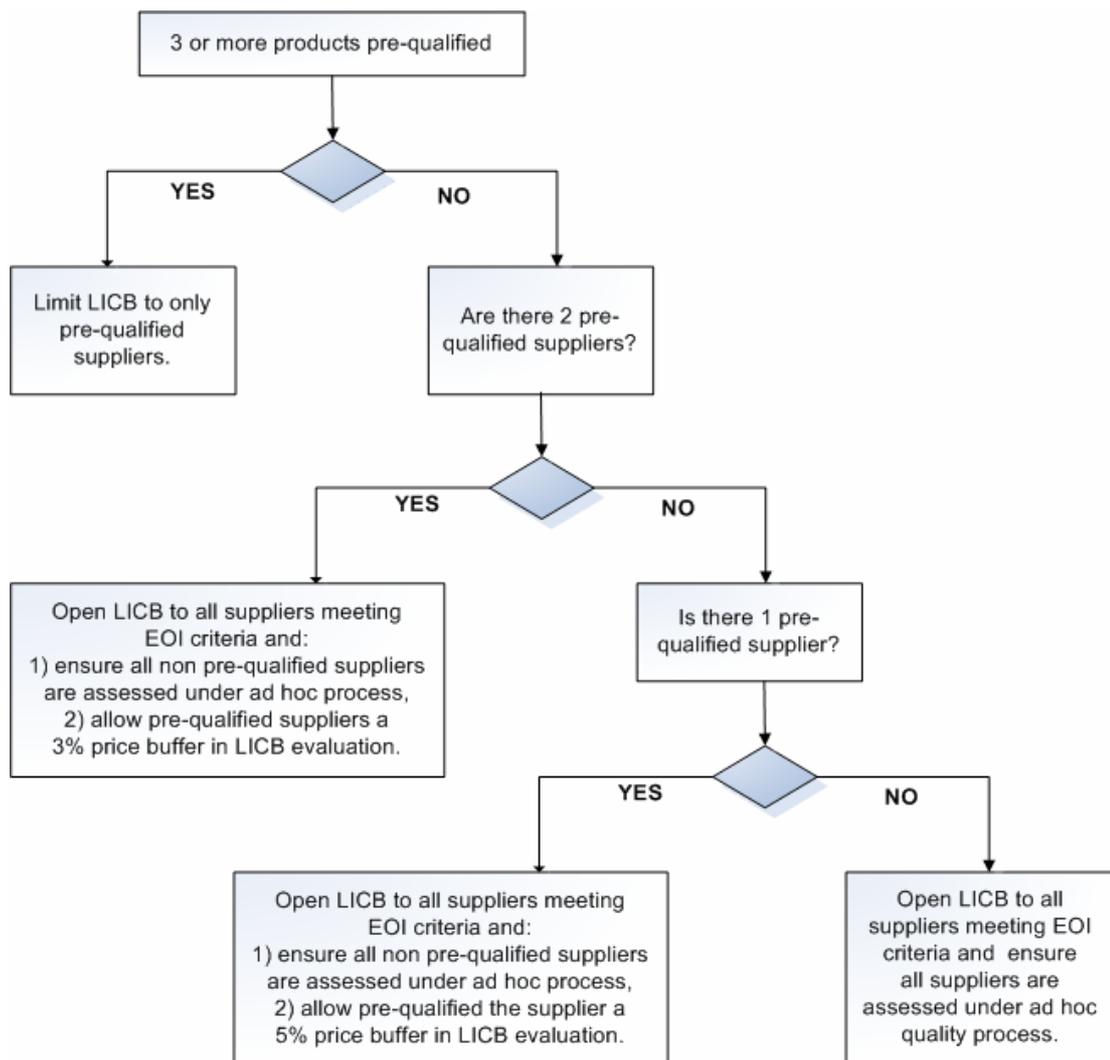
An LICB is issued to four suppliers for a single product; one of the four suppliers has gained prequalification under the WHO TB Prequalification Project; the other three have not but have been considered as acceptable to bid through the ad hoc assessment of their dossiers. As price is one of the key evaluation criteria for the LICB process then the supplier with a prequalified product could have a price 5% higher than the other three suppliers but still be considered to have the same price. i.e. the submitted prices are as follows:

|                                  |         |
|----------------------------------|---------|
| Supplier One (prequalified)      | \$21.00 |
| Supplier Two (not prequalified)  | \$23.00 |
| Supplier Three(not prequalified) | \$21.00 |
| Supplier Four (not prequalified) | \$20.00 |

The prices of Supplier One and Supplier Four would be considered to be the same since Supplier One is awarded a 5% buffer for being the only competitor with a prequalified product.

The flow diagram below is provided to indicate where and in which situations the ad hoc quality assessment process would be implemented and where and to what extent the prequalification price buffer would be awarded to prequalified suppliers.

**Proposed Process for Identification of use of the ad hoc process and price buffer rewards for suppliers which have obtained prequalification under the WHO TB Prequalification Project**



## **Summary**

A number of products used in the 1<sup>st</sup> line treatment of tuberculosis have not obtained prequalification under the WHO TB Prequalification Project. The reasons for this include both supplier reticence and a sub-optimal capacity to assess all the applications submitted to the WHO TB Prequalification Project.

The GDF proposes a multi-pronged approach to promote the WHO TB Prequalification Project to suppliers and to assist the GDF in making evidence based awards for supply in the case where prequalification has not be obtained.

The GDF proposes to reward suppliers which have gained prequalification under the WHO TB Prequalification Project by allowing their prices submitted in LICB to be up to 3% and 5% higher than non prequalified competitors depending on the number of prequalified competitors that are engaged in the LICB process.

The GDF proposes to enhance its current ad hoc assessment criteria, for products not prequalified under the WHO TB Prequalification Project, in order to make an evidence and risk based decision on the quality of products submitted in the LICB processes.

The GDF request the support from the Board to further advance the cause of GDF with the WHO Prequalification team to try to promote efficient assessment of TB products through the WHO TB Prequalification Project.

## **Decisions requested from the Stop TB Coordinating Board**

- Approve the proposed process for obtaining an interim assessment of quality of a product for supply for Grant and Direct Procurement recipients in the absence of the product having prequalification under the WHO TB Prequalification Project.
- Approve the proposed process for prioritization of products that have obtained prequalification under the WHO TB Prequalification Project.
- Resolve to further advance the cause of GDF with the WHO Prequalification team to try to promote efficient assessment of TB products through the WHO TB Prequalification Project.