



**A NEW  
PERSPECTIVE  
ON TB DRUG  
PROCUREMENT.**

## **AD HOC INVITATION FOR EXPRESSIONS OF INTEREST (EOI)**

**For Paediatric and Single anti-tuberculosis drug formulations  
November 2005**

In the context of facilitating access to anti-tuberculosis drugs for use in countries with a high burden of tuberculosis, WHO, together with the Stop TB Partnership's Global Drug Facility (GDF), are inviting **Expressions of Interest**, from manufacturers of such pharmaceutical products. For more information please refer to the web-site: [www.stoptb.org/GDF](http://www.stoptb.org/GDF)

Interested **manufacturers or their authorized agents** are invited to submit their expressions of interest to UNICEF Supply Division for the following products:

Formulations for children:

Dosage forms should be soluble tablets, tablets with break line, and/or sachets:

- 1) **Rifampicin 60 mg /Isoniazid 30mg/ Pyrazinamide 150 mg (R60/H30/Z150)**
- 2) **Rifampicin 60 mg /Isoniazid 30mg (R60/H30)**
- 3) **Rifampicin 60 mg/ Isoniazid 60 mg (R60/H60)**

Single formulation tablets:

- 4) **Rifampicin 150 mg**
- 5) **Isoniazid 50 mg**
- 6) **Isoniazid 100 mg**
- 7) **Ethambutol 100 mg (coated tablets)**
- 8) **Pyrazinamide 150 mg**

The medicines listed in this Invitation for Expression of Interest are those for which a need has been identified by the Stop TB department, WHO.

Products should be made available in different pack sizes: in blister packs in carton boxes, aluminium strips or sachets in carton boxes and loose tablets in suitable containers e.g. HDPE.

The submitted products should be of assured pharmaceutical quality and relevant data to support efficacy should be provided.

Procedure for submission of EOI:

1. Submit a covering letter expressing the interest to participate in the *ad hoc WHO assessment procedure*, confirming that the information submitted in the product dossiers is true and correct.
2. Submit a product dossier in the recommended format as specified in the Guideline for submission of a product file which is also on the web page <http://mednet3.who.int/prequal/>. The dossier should be accompanied by a sample of the product to enable analysis (e.g. 1 x 100 tablets).\*

\*If the dossier is compiled in a different format (e.g. EU), then such a dossier can be submitted with a covering letter cross-referencing the pages where the relevant data can be found in accordance with the above mentioned Guideline.

\*It is understood that for one or more of the products 1-8 listed above it may not be presently possible to submit a complete product dossier as per the WHO Guidelines indicated at <http://mednet3.who.int/prequal/>. Nonetheless, product dossiers should be



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compiled as per these Guidelines to the greatest extent possible *BUT at a minimum must comply with the information requested in Annex 1 to this EOI: Pharmaceutical Product Questionnaire*

Note: If a product dossier has already been submitted for any of products 1, 2 and/or 3 above as a part of the TB Prequalification Project implemented by WHO, interested manufacturers or their authorized agents are requested to indicate which dossiers have been submitted for which products and to submit any updated information, as necessary per dossier (since the last submission).

Submitted documentation should reach UNICEF Supply Division before **Friday 25<sup>th</sup> of November** at close of business, for evaluation during the following week. GDF, through its Procurement Agent UNDP/IAPSO ([www.iapso.org](http://www.iapso.org)), intends to launch a Limited International Competitive Bid (LICB) for these products by mid December 2005. Only products assessed during this product dossier evaluation may be eligible to be offered in the LICB of December 2005.

Interested manufacturers should submit the above-mentioned information to:

UNICEF Supply Division  
Reference: AD HOC ANTI-TUBERCULOSIS PRODUCT DOSSIER EVALUATION  
PAEDIATRIC FORMULATIONS/MONO-SUBSTANCES  
WHO/GDF/STOP TB PARTNERSHIP  
UNICEF Plads-Freeport  
DK-2100 Copenhagen  
Denmark  
E:mail: [supply@unicef.org](mailto:supply@unicef.org)  
  
For attention: Dr. O. Gross  
  
Tel: (45) 35 27 35 27  
Fax: (45) 35 26 50 48

3. Submit a Site Master File for each manufacturing site as listed in the product dossier, in the recommended format, also available by electronic mail and on the web page <http://mednet3.who.int/prequal/>, to Mrs Carolyn Doucelin, WHO/HTP/PSM/QSM, 20 Ave Appia, 1211 Geneva, 27 Switzerland.
- A. **Product dossiers submitted will be assessed by WHO for compliance with WHO standards as specified in the Official Guidelines and in the absence thereof, compliance with the Pharmaceutical Product Questionnaire (See Annex 1 to this EOI) and;**
- B. **Manufacturing sites will be assessed for compliance with WHO GMP as assessed under the TB Prequalification Project and/or by a stringent National Regulatory Authority party to the Pharmaceutical Inspection Cooperation Scheme:** <http://www.picscheme.org/> or ICH: International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use.
- C. Products and manufacturing sites, found to meet the aforesaid standards, will be invited to bid for the supply of products, individually or collectively, directly by the GDF.

The following criteria will be taken into account in the quality assessment process:



Global TB Drug Facility / Stop TB Partnership  
c/o World Health Organization, 20 avenue Appia, CH-1211 Geneva 27, Switzerland  
Fax: + 41-22-791 4486 or + 41-22-791 4886

Email: [gdf@stoptb.org](mailto:gdf@stoptb.org) - Website: [www.stoptb.org/gdf](http://www.stoptb.org/gdf)

The Stop TB Partnership Secretariat is housed by the World Health Organization



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- Valid manufacturers license for production.
- Product registered or licensed in accordance with national requirements.
- Products manufactured in compliance with GMP as certified by the national regulatory authority and /or certified GMP inspectors.
- Product certificates exist in accordance with the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.
- Product dossiers submitted found to meet be complaint with WHO standards as specified in the Official Guidelines and in the absence thereof, compliance with the Pharmaceutical Product Questionnaire (See Annex 1 to this EOI.
- Manufacturing sites found to be compliant with WHO GMP as assessed under the TB Prequalification Project and/or by a stringent National Regulatory Authority party to the PIC/S Scheme or ICH.
- Manufacturer demonstrates sound financial standing.

By submitting an expression of interest for participation in the *ad hoc quality assessment process*, a manufacturer represents that it can supply appropriate products compliant with national laws and regulations, including but not limited to regulatory requirements. WHO reserves the right to exclude a manufacturer from participation in the *ad hoc quality assessment process* in the event that this condition is not, or no longer, complied with.

WHO and GDF reserve the right to require compliance with additional conditions, as and when they invite manufacturers included in the list to bid for the supply of products or as and when contract awards are issued subsequent to conclusion of the LICB.

#### References

For the WHO TB guidelines please refer to the following link:

[http://www.who.int/tb/publications/cds\\_tb\\_2003\\_313/en/](http://www.who.int/tb/publications/cds_tb_2003_313/en/)

**Please address any questions related to this EOI to:**

Hugo Vrakking: [vrakkingh@who.int](mailto:vrakkingh@who.int)

Robert Matiru: [matirur@who.int](mailto:matirur@who.int)

Matthias Stahl: [Stahlm@who.int](mailto:Stahlm@who.int)