

**SIXTH INVITATION FOR
EXPRESSION OF INTEREST (EOI)
Antituberculosis
May 2005**

In the context of facilitating access to anti-tuberculosis drugs for use in countries with a high burden of tuberculosis (TB), WHO, together with other UN agencies participating in the Stop TB Partnership, with its Global Drug Facility (GDF), i.e. UNICEF, UNAIDS, UNFPA and the Green Light Committee, are inviting **Expressions of Interest**, from manufacturers of such pharmaceutical products. For more information please refer to the web-site: www.stoptb.org/GDF and the web-sites of the above mentioned organizations.

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

- 1) Ethambutol Hydrochloride 400mg film coated tablets
- 2) Pyrazinamide 400mg tablets
- 3) Isoniazid 300mg tablets
- 4) 2FDC: Rifampicin 150 mg /Isoniazid 75mg film coated tablets
- 5) 2FDC: Rifampicin 150 mg /Isoniazid 150mg film coated tablets
- 6) 2FDC: Ethambutol Hydrochloride 400 mg /Isoniazid 150mg film coated tablets
- 7) 3FDC: Rifampicin 150 mg / Isoniazid 75 mg / Ethambutol Hydrochloride 275 mg film coated tablets
- 8) 4FDC: Rifampicin 150mg /Isoniazid 75mg /Pyrazinamide 400mg /Ethambutol Hydrochloride 275mg film coated tablets
- 9) Streptomycin Sulfate 1g vial (injection)
- 10) Water for injection 5ml vial (injection)
- 11) Amikacin 500mg/2 ml vial (injection)
- 12) Kanamycin 1g powder for injection, vial
- 13) Capreomycin 1g powder for injection, vial
- 14) Cycloserine 250mg capsules
- 15) Ethionamide 125 mg or 250mg tablets
- 16) Ofloxacin 200 mg tablets
- 17) Prothionamide 125 mg or 250mg tablets
- 18) Para-aminosalicylic acid 4 g granules and para-aminosalicylic sodium 100 g granules

Formulations for children.

Dosage forms should be soluble tablets, tablets with break line (film coated), and or sachets.

- 1) 3FDC: Rifampicin 60 mg /Isoniazid 30mg/ Pyrazinamide 150 mg
- 2) 2FDC: Rifampicin 60 mg /Isoniazid 30mg (R60/H30)
- 3) 2FDC: Rifampicin 60 mg/ Isoniazid 60 mg (R60/H60)
- 4) Isoniazid 100mg tablets

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

WHO, together with other UN agencies participating in the Stop TB Initiative, with its Global Drug

Facility (GDF), i.e. UNICEF, UNAIDS, UNFPA and the Green Light Committee are especially interested in receiving Expressions of Interest for the possible procurement and supply of these products. Products should be made available in different pack sizes: in blister packs 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 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 can be obtained by electronic mail from aduk@who.int, doucelinc@who.int, or griffing@who.int, also available on the web page <http://mednet3.who.int/prequal/>. The dossier should be accompanied by a sample of the product to enable analyses (e.g. 1 x 100 tablets or 1 x 5/10 vials).

* Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies.

** 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.

Submitted documentation reaching UNICEF Supply Division will be evaluated during March, May, July, September, and November 2005. Documentation should be provided in English.

Interested manufacturers should submit the above-mentioned information to:

UNICEF Supply Division Reference: Access to anti-tuberculosis products, 6 th EOI UNICEF Plads-Freeport DK-2100 Copenhagen Denmark E:mail: 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/EDM/QSM, 20 Ave Appia, 1211 Geneva, 27 Switzerland.

Product dossiers submitted will be assessed by WHO for compliance with WHO recommended standards, and manufacturing sites will be assessed for compliance with WHO GMP. Products and manufacturing sites, which will be found to meet the aforesaid standards, will be included in a list of suppliers whose products are considered acceptable in principle for procurement by UN

Agencies. Products and manufacturers included in this list may be invited to bid for the supply of products, individually or collectively, directly by the aforesaid UN agencies. For full details see www.stoptb.org/GDF product list.

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

- 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 WHO recommended standards as a result of the assessment process.
- Manufacturing sites found to meet WHO recommended standards as a result of the assessment process.
- Manufacturer demonstrates sound financial standing.

By submitting an expression of interest for participation in the 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 quality assessment process, or to remove a manufacturer from the above-mentioned list, in the event that this condition is not, or no longer, complied with.

The above mentioned UN agencies 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.

References

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

http://www.who.int/tb/publications/cds_tb_2003_313/en/