



## GLOBAL DRUG FACILITY

### Expression of interest for manufacturers of Second-line anti-TB drugs (finished dosage form products)

The Global Drug Facility (GDF), an initiative of the Global Partnership to Stop TB hosted by the World Health Organization, is looking to increase the access to quality, affordably priced second-line anti-TB drugs to be supplied to Green Light Committee (GLC) approved programs.

The GDF in collaboration with the USP (United States Pharmacopeia) and USAID (US Agency for International Development) is interested to receive Expressions of Interest from manufacturers of second line anti-TB drugs who would benefit from **receiving technical assistance** to enable them to rapidly conform to WHO recommended standards.

Manufacturers for the following products are encouraged to submit their expression of interest to the Global Drug Facility for technical assistance:

- Capreomycin 1 g, powder for injection
- Kanamycin 1 g, powder for injection
- Para-amino salicylic acid 4 g or its sodium salt 100 g, coated-granules

The technical assistance covers the categories listed below:

- manufacturing second-line anti-TB drugs in general compliance with the principles and guidelines of WHO Good Manufacturing Practices
- preparing product dossier for submission for approval to the WHO Prequalification Project (link to web-site: <http://mednet3.who.int/prequal/>)

Interested manufacturers should send a cover letter of interest with the **attached questionnaire (Annex 1)** duly completed to the following address:

**Global Drug Facility  
C/o STOP TB, World Health Organization Geneva  
Attn: Vitalis Adu  
20, Avenue Appia  
CH-1211 Geneva 27  
Switzerland**

before 29 **October 2007 (17:00 Geneva, Switzerland)**.

Submitted documentation reaching the Global Drug Facility will be evaluated on an on-going basis. Documentation should be provided in English. Expressions of interested submitted without a completed questionnaire and related documentation may not be considered.

Interested manufacturers who have any queries about this EOI should contact GDF at: [milanib@who.int](mailto:milanib@who.int) and [matirur@who.int](mailto:matirur@who.int)

The evaluation will be based on the following criteria in the selection process for technical assistance:

1. Complete documentation as requested in the Questionnaire Form with a confirmation that the information provided is true and correct.
2. Valid manufacturers license for production.
3. Product registered or licensed in accordance with national requirements.
4. Manufacturer demonstrates sound financial practices.

**Disclaimer:**

- *Submitting an Expression of Interest and related documentation does not guarantee that any technical assistance will be provided by GDF or its partners*
- *receiving technical assistance does not guarantee purchases from the GDF*
- *receiving technical assistance does not guarantee that the manufacturer and their products will be successfully pre-qualified by WHO*