

## **Stop TB Working Group on MDR-TB**

### **Drug Management Sub-Committee of Working Group**

#### **I. Terms of Reference – Mandate and Activities Next 3 Months**

1. Complete and Refine the Definition of the problem and the threat posed by the Shortage of QA 2<sup>nd</sup> line medications, building on Tbilisi presentation and discussion.
2. Complete the Specific Quantification of the current Shortage of 2<sup>nd</sup> line meds for approved-GLC projects (Early October data gathering, late October deliberation and finalization at next GLC meeting).
3. Create a Draft Plan of Action for consideration and approval by the Core Group at a to-be-scheduled next meeting in Capetown.
4. Take specific short-term steps to implement the Plan of Action ASAP
  - a. Work with WHO colleagues to get an ADG-level meeting (between October 7 -19<sup>th</sup>) to clarify crisis, set priorities and get resolution on staffing and pre-qualification commitments from EDM
  - b. Set meetings with important suppliers of critical medications November 5-12 (MacLeods, Lupin, Sanofi-Aventis, Aspen, Lilly, Bayer, beneficiaries of Lilly-technology transfer). Supplement with informal conference calls, if need be.
  - c. Start informal meetings (by conference call, as needed, prior to October 15<sup>th</sup>) with GFATM (Sr. Advisor to Executive Director, Procurement/Operations Group) and UNITAID (Procurement Officer, Ops Coordinator and Sr. Advisor) to inform them of the issues, the proposals under consideration for resolution; seek input as to what they may or may not support; this needs to happen
  - d. Secure time-slot on Agenda for October (Berlin) meeting of the Stop TB Partnership Coordinating Board
  - e. Prepare presentation for that meeting that defines the crisis, potential solutions and needed support
  - f. Draft letters from Stop TB CB to WHO, UNITAID, GFATM

## **II. Terms of Reference – Ongoing Responsibilities and Mandate**

1. Oversee Implementation of the Plan of Action, with regular quarterly reports to the Core Group on clear and specific Progress Indicators.
2. Lend Support GLC and GDF efforts to improve in-country management of second-line anti-TB drugs with respect to quantification, importation, registration, distribution and storage through:
  - development of improved and standardized quantification tools,
  - development of standardized monitoring and evaluation tools for in-country drug management and,
  - participation in drug management training workshops.
- Identify resources to fund technical assistance to manufacturers that want to become compliant with WHO's norms and standards, including standards for quality supply of second-line anti-TB drugs.
- Advise WHO/STB on strategies to promote a smooth supply of quality assured second-line anti-TB drugs to meet the demands of the global scale up of MDR-TB management, according to the Global Plan to Stop TB 2006-2015.
- Collaborate with the GLC in promoting sound management of second-line anti-TB drugs, in line with WHO guidelines.
- Assist the Stop TB *Task Force on Market Dynamics*, in collaboration with the GDF Business Advisory Committee, in developing strategies to:
  - catalyse prequalification of second line anti-TB drugs thereby increasing the competitive pool of manufacturers and the capacity for production of second-line drugs,
  - decrease the prices of second-line anti-TB drugs for better accessibility, including further price reductions for products offered by current suppliers of the GLC Initiative and,
  - develop market intelligence on existing and potential new sources of second-line anti-TB finished product formulations and Active Pharmaceuticals ingredients.

## **II. Proposed Membership of sub-group**

The proposed list of members is based on preliminary expressions of interest already made by GLC partners and an attempt to ensure a balance of expertise from among WG partners.

- *Country representatives (National TB control Programs)*
- *KNCV*

- *Management Sciences for Health*
- *Médecins sans Frontières*
- *Partners in Health*
- *Project Hope*
- *GLC Chair (or designate)*
- *WHO (Dept. for Essential Drugs and Medicines)*
- *WHO (STB/THD)*

### **III. Proposed Timetable of activities**

- i. Finalization and endorsement of TOR and membership at the 6th meeting of the Stop TB Working Group on MDR-TB (WG) to be held in Tbilisi Georgia from 20 to 22 September 2007.
- ii. First meeting of the sub-group in association with the IUATLD Congress in Cape Town, 8 – 12 November 2007 to determine a work plan and schedule of operation and activities for 2008.