SUMMARY SHEET			
Agenda Nr. 2.07-7.0	Subject	**TB Drug Supply - overcoming procurement bottlenecks**	
For Information ☐	For Discussion ☒	For Decision ☒	

Rationale:

- There is a severe imbalance in the supply-demand dynamics for *second-line line anti-TB drugs*. The scale of the imbalance, however, is unclear and the factors behind it vary from country-to-country. There is a global shortage of quality assured second-line TB drugs for patients in approved Green Light Committee programs.
- Country shortages for *first and second line drugs* often result from the global shortage. Shortages are also caused or amplified by registration restrictions and import barriers of governments, poor forecasting and order placement by programs, complicated, time-consuming financial transactions between partners and agents, and delays in disbursements from donors and financing mechanisms.

Roles of Key Actors

- Green Light Committee (GLC) – Responsible for reviewing, assisting, approving and monitoring and evaluating MDR-TB management programmes; approval allows release of Global Fund and UNITAID monies for purchase of second-line drugs; the GLC is not responsible for drug procurement.
- Global Drug Facility (GDF) – Responsible for providing drug forecasts to procurement agents and suppliers; contracting procurement agents; ensuring, via contracted agents/suppliers, delivery of drugs to GDF and GLC-approved programs; ensuring the high quality of drugs supplied.
- The World Health Organization (WHO) Department for Essential Drugs and Medicines Policy (EDM) – Responsible for pre-qualification of suppliers and products to ensure that products meet international standards of quality before they are procured.
- GDF and GLC approved programs and governments – Responsible for planning patient enrolment and treatment; forecasting drug needs; communicating forecasts and delivery schedules to procurement agents; coordinating with financing mechanisms to ensure payment in advance of supply; facilitating timely registration and importation of drugs; properly managing drugs received.
- Donors and financing mechanisms (governmental and non-governmental) e.g. Global Fund (GF) and UNITAID – Responsible for approving and overseeing expenditures; releasing funds upon demand; advocating with other key actors to eliminate bottlenecks to ensure the greatest possible impact.
- Manufacturers of finished products and APIs: Receipt of orders for drugs; timely delivery at reasonable prices.

Summary:

CORE PROBLEMS

<u>I. Opaque Market</u>

- Administrative barriers and costs of entry, uncertain returns for suppliers;
- Delays in placement, payment or receipt of orders;
- Little accurate, reliable quantification of current global demand (*Particularly for second line drugs)*;

- No standardized process for short- and longer-term forecasting;
- Inability to estimate the timing and reliability of demand by individual recipients (programs and governments);
- No strong player to assure rapid payment and assume risk e.g. for advance purchase commitments.

II. Short-term paralysis in flow of 2nd line drugs

- Demands for high quality second-line drugs currently outstrips capacity;
- Sub-optimal logistics, communications and response-time between key actors has exacerbated supply shortages;
- Lack of firm demand forecasts and sporadic order placement means irregular manufacturing stream;
- Inadequate GLC-approved supply impacts disbursements and overall programme performance.

III. Barriers, Costs of Entry & Uncertain Returns for Industry

- Technical requirements of production and high capital cost, scarcity of raw materials;
- Shelf-life risks (*Particularly for second line drugs)*;
- Expensive and slow pre-qualification and approval process;
- High costs of country registrations and import licenses;
- Registration used as to protect local industry;
- More attractive, predictable, captive, domestic and international markets

Decisions Requested (from the Stop TB Coordinating Board)

1. Acknowledge the second-line drug access challenges as a *Crisis* negatively affecting patients, programs, GF funding and the future relevance of GLC. Ensure the crisis is addressed by the Stop TB Partnership with the appropriate sense of urgency.
2. Acknowledge that the power to resolve the crisis is held by entities in different organizations, answering to different authorities and that clear lines of responsibility and accountability are required. Agree to press at the highest levels of WHO, GF and UNITAID to establish priorities, assign direct responsibilities and allocate resources.
3. Recognize that the Committees working with GDF e.g. Business Advisory Committee, Task Force on TB Market Dynamics and MDR-TB sub-group on Drug Management, while important in their own right, are an insufficient response. The complexity and extent of the work requires dedicated, full-time professionals and funding. Agree on how the Board will support the resolution of the GDF and GLC secretariat staffing shortages as a matter of urgency.
4. Endorse the recommendations of Working Group on MDR-TB that met in Tbilisi, Georgia 20-22 September and comprehensively discussed key procurement bottlenecks and recommended action steps with respect to second-line drugs.
5. Endorse the recommendations of the GDF Business Advisory Committee that met 3-4 October and comprehensively discussed key procurement bottlenecks and recommended action steps.

Implications (political/financial/staffing etc)**:**

- Relevance of GLC at stake
- Reputation of GDF and role in first and second-line line drug procurement at risk
- Global Fund funding for important GLC-approved programs at risk
- High level discussions with Global Fund and UNITAID on options and solutions necessary
- High level negotiation with WHO required to resolve staffing and prequalification bottlenecks

Next Steps

Action Required:

- Letters from the CB to WHO Director General, Global Fund Executive Director
- Meetings of high level delegation of CB with WHO Director General, Global Fund Executive Director, UNITAID Executive Secretary

Focal Points: Executive Secretary, STB Director, GDF and GLC secretariats

Timeframe: Short-term actions: Oct. to Dec. 2007; medium term actions Jan. to Dec. 2008.