

# Access to and Management of 2<sup>nd</sup>-Line Drugs

Sixth Meeting, STB Working Group of MDR-TB  
20-22 September 2007 - Tbilisi

# Summary

1. Severe shortage of 2<sup>nd</sup>-line meds
2. Separate Roles of Key Actors
3. Core Problems

# Severe shortage of 2<sup>nd</sup>-line meds (1)

- There is a severe imbalance in the Supply-Demand for 2<sup>nd</sup> line medications
- This is a global shortage
- There are inadequate # medications (QA) for patients in the active GLC projects, in the currently-approved GLC projects
- We do not know the specific amounts of the imbalance, current and future.

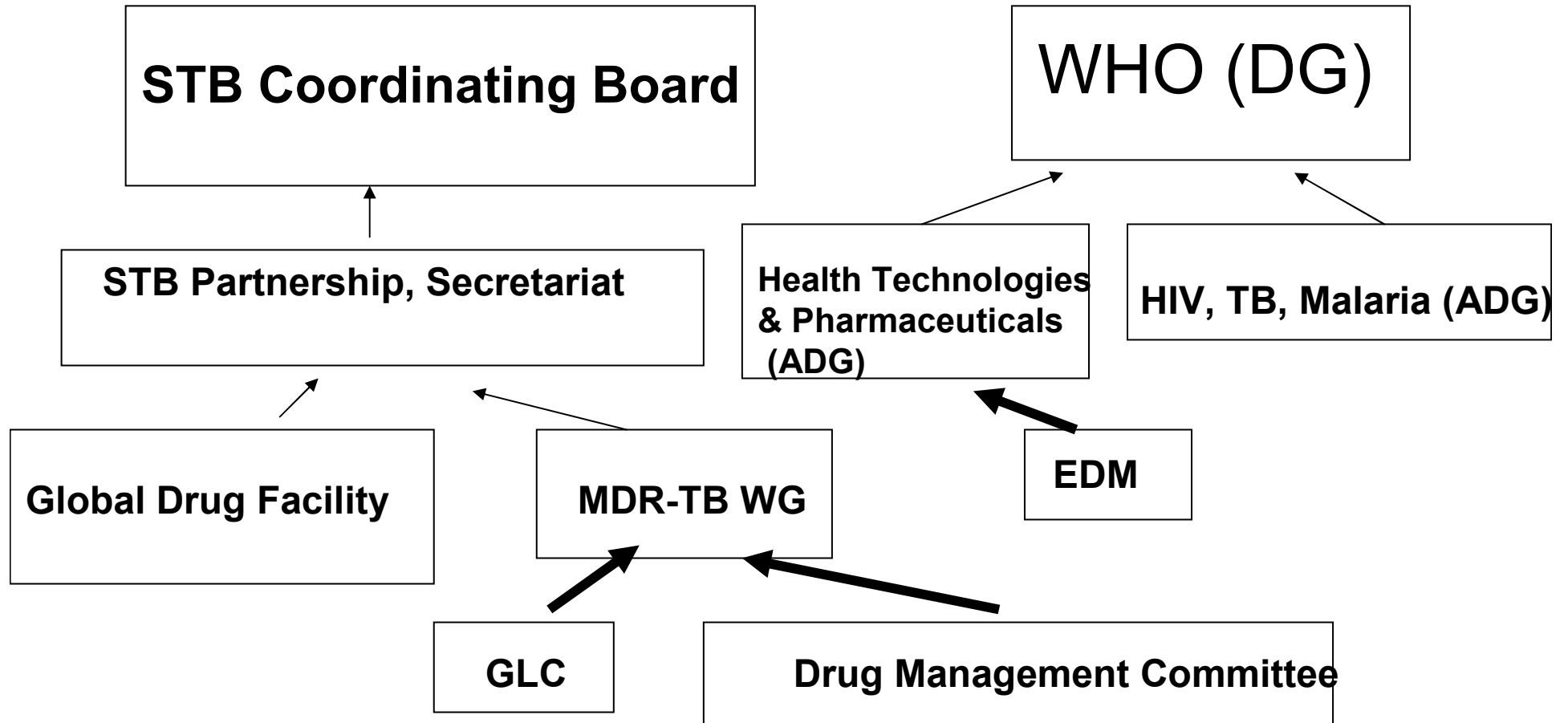
# Shortage of 2<sup>nd</sup>-line meds (2)

- There are national, project shortages created by limits on Available Supply in particular countries.
- This results partly from the global shortage, but:
- It is made much worse by registration restrictions, import barriers of governments
- It is also made worse by poor forecasting and communication of need by projects, delays in order placement by Principal Recipients, etc.
- We do know the specific amounts of the imbalance for certain projects, but not for others.

# Separate Roles of Key Actors

- **GLC** – Responsible for project approval; approval allows release of GFATM & UNITAID \$; GLC not responsible for meds
- **GDF** – Responsible for forecasts, contracts, IDA, procure meds to projects
- **EDM** – Responsible for pre-qualification of suppliers, approval of products
- **Others:** projects, PR's, nat'l govt's, etc

# Separate Lines of Authority



# Core Problems

1. Opaque Market
2. Short-term Paralysis in flow of meds
3. Barriers, Costs of Entry, Uncertain Returns
4. Delays, inadequate staffing, lack of funding, urgency, activity and clear lines of responsibility among key players

# Core Problem (1): Opaque Market

- No accurate, reliable quantification of current demand
- No process for short- and longer-term forecasting
- Inability to estimate the timing and reliability of demand
- No strong player to assure payment and assume risk

## Core Problem (2): Short-term Paralysis in flow of meds

- System is locked up
- Logistics, communications and response-time to and from GLC, GDF, IDA and the projects, exacerbated supply shortages
- No firm demand forecasts .... little supply
- Inadequate approved supply .... no release of funds

## Core Problem (3) – Barriers, Costs of Entry & Uncertain Returns

- Technical requirements of production & high capital cost, scarcity raw materials
- Shelf-life risks
- **Expensive & slow pre-qualification and approval process**
- **High costs, barriers of country registrations and import licenses, etc**
- **More attractive, predictable, captive, domestic and international markets**

## Core Problem (4): Urgency, Staff, \$ & Clear Lines of Responsibility

- Crisis has not been acknowledged and addressed with appropriate sense of urgency. MDR-TB drugs have not been made a priority.
- Power to resolve the crisis held by people in different organizations, answering to different authorities. There are no clear lines of responsibility and accountability.
- Committees working with GDF are an insufficient response. The complexity and extent of the work requires dedicated, full-time professionals and funding

# Review/Endorsed by WG Members

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- Agnes Gebhard
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- Einar Heldal
- Wieslaw Jakubowiak
- Joel Keravec
- Salmaan Keshavjee
- Kitty Lambregts
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- Jacques Van Den Broek
- Paul Zintl

Thank You