Quality-Assured Second-Line TB Medicines:

*Drug Management and Market Risk*

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April 2011
Overview

This presentation will focus on:

- The relationship between MDR drug management and a strong quality-assured drug marketplace
- How a strong drug management strategy can:
  - Manage risk;
  - Lower price;
  - Increase availability
- Why such a strategy must be global in scope
The vision: a “virtuous cycle” of MDR-TB drug marketplace improvement

**“Demand” side**
- Case-finding
- Drug orders
- Aligned in-country scale-up

Larger market potential due to higher enrollment

**“Supply” side**
- Higher volumes
- Lower prices
- Iterative negotiations

Higher enrollment capacity due to price reduction

Overall scale-up strategy
The reality: a global marketplace that is largely stalled

- Case-finding is limited by low drug stocks
- Drug orders are limited by low case-finding
- "Supply" side averse to risk of making drugs that aren’t purchased
- "Demand" side averse to risk of purchasing drugs that aren’t used
- Suppliers opt not to scale up because of historically low order volumes
- Orders remain low due to high prices
Risk management in the MDR-TB drug marketplace

- MARKET RISK
  - Quantify
  - Aggregate
  - Share
Quantifying risk: the problem with target-based forecasting

2009 GDF Injectibles Forecast (issued 2008)

Unfulfilled: 63%
Actual: 37%

Forecast (11940 patients)
Quantifying risk: a more transparent approach

Risk factors:
- Funding availability
- Case-finding rates
- Drug sensitivity trends
- Programmatic hurdles

Two purposes:
- Optimal ordering processes (internal)
- Market transparency (external)
Aggregating risk: importance of a global approach

(Hypothetical example)

Country A:

Country B:

Country C:

Country D:
Aggregating risk: components of a global approach

Key requirements:

- A centralized aggregating entity
- A credible global forecasting mechanism
  - Two-way information flow
  - In-country technical partnership
- A virtual rotating stockpile

This does not necessarily imply centralized global procurement
Levers for risk sharing:

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Summary: key strategic questions

- **Who** is involved in developing and executing a strategy to address market risk in quality-assured MDR-TB drugs?

- **How** is this process approached?

- **What** information and resources are required on a continuing basis?