



Global Drug Facility Green Light Committee

Provision of TB drugs

Münchenwiler TB Symposium, March 22, 2007

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GDF and GLC

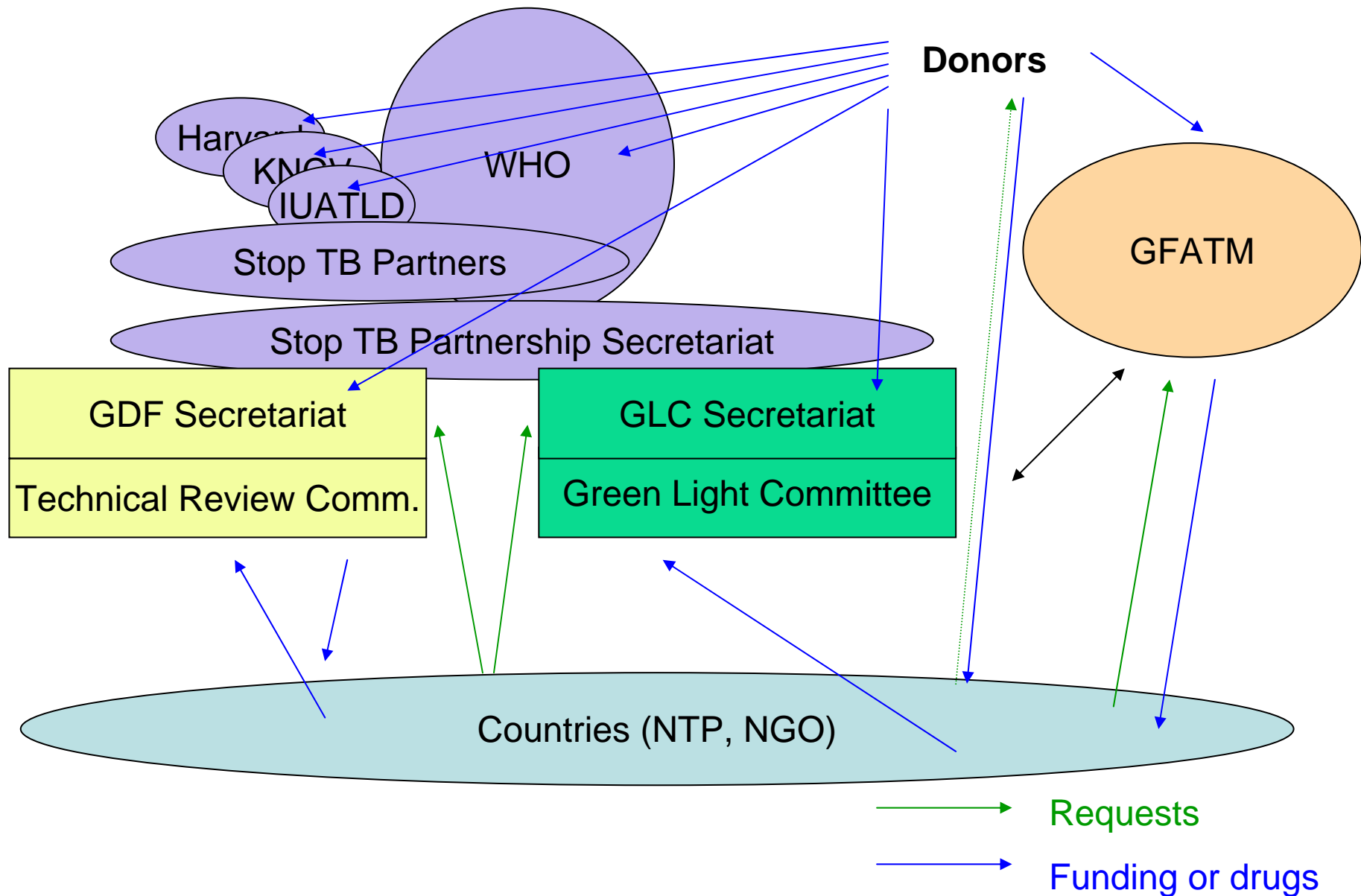
- Non-profit organisations
- Provision of quality-assured TB drugs
- Technical advice through country visits
- Secretariats hosted by WHO in Geneva
- Rely on partners of the Stop TB Partnership
- Will eventually merge

GDF and GLC -- Differences

	GDF	GLC
Strategy	DOTS	DOTS plus
TB drugs	First line*	Second line*
Provision	Grant and sale	Sale

* Joint procurement after 2006

GDF - GLC - GFATM

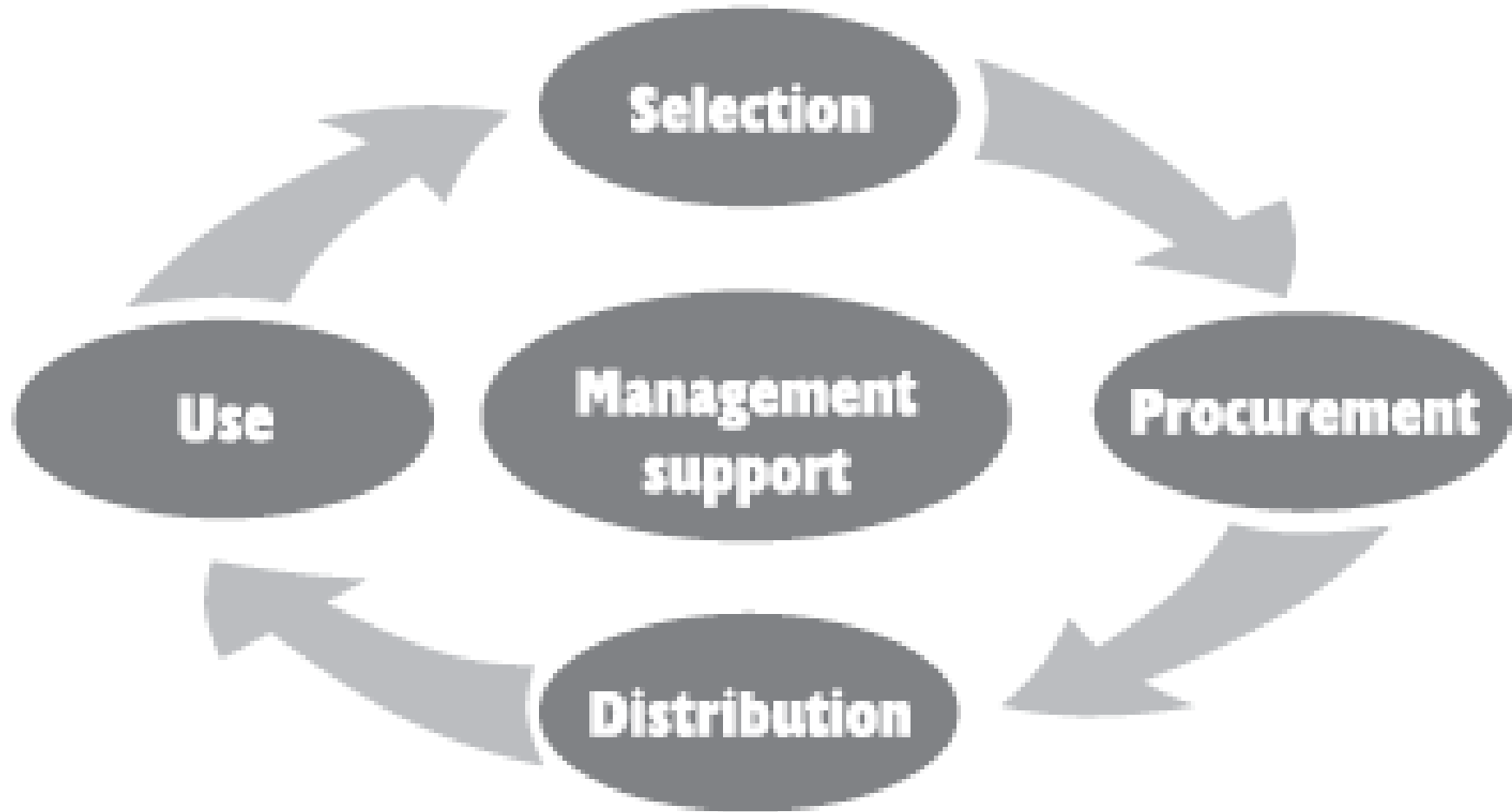


What is the DOTS strategy?

DOTS is the internationally recommended strategy for TB control, comprising:

- Sustained political commitment
- Quality-assured TB sputum microscopy
- Standardized short-course chemotherapy for all cases of TB under proper case-management conditions, including direct observation of treatment
- Uninterrupted supply of quality-assured drugs
- Recording and reporting system assessing every patient and overall programme performance

Drug management cycle



Some drug management problems

1. Selection

Quality

~ Standard treatment regimens:

2(RHZE)/4(RH) vs 2(RHZE)/4(RH)₃

e.g. RH 150/75 vs. RH150/150

2. Procurement

Irregular ~ funding

Procedures ~ country, funding

Some drug management problems

3. Distribution

Customs clearance

Irregular to periphery (no transport)

Non-standard calculations

Storage, FEFO, stock-outs

4. Use

Dosage errors

Default rates

Why do we need a GDF?

Problem	GDF Response
Lack of resources	→ GDF Grant Service: first-line adult and paediatric anti-TB drugs
Inefficient procurement mechanisms	→ GDF Direct Procurement Service
Inadequate quality assurance	→ WHO TB Prequalification Programme
Non-specific international recommendations	→ Limited list of standardized products and packaging (fixed-dose combination tablets and patient kits)
Non adherence to international recommendations	
Diversity of products	
Inadequate in-country management and monitoring	→ Facilitate technical assistance (TB and drug management) from partners through the GDF Technical Support Service

GDF grants: Free drugs for DOTS

ELIGIBLE COUNTRIES

- Annual per capita GNP under US\$ 3000
- National plan and budget for DOTS expansion
- Technical guidelines: principles of DOTS
- Annual report on DOTS performance (WHO TB collection form)
- Recent external national TB programme review

GDF PROVIDES DRUGS

- In principle for three years
- Each year's grant is based on technical monitoring visit

Global Drug Facility

Buying high-quality TB drugs through GDF's
DIRECT PROCUREMENT MECHANISM

- Price
- Quality
- Regular monitoring and technical support

DIRECT PROCUREMENT ELIGIBILITY CRITERIA

1. Countries implementing the DOTS strategy in 90% or more of the population & NGOs supporting DOTS in these countries.
2. Countries or NGOs approved by the Global Drug Facility for a grant of free TB drugs.
3. Countries or NGOs approved for a grant for tuberculosis control by the Global Fund to fight AIDS, Tuberculosis & Malaria.
4. Organizations, donors and technical agencies supporting the above categories of countries or NGOs.

Technical monitoring visits

- 6 months after arrival of GDF drugs
- By independent TB program and drug management experts

- Adherence to GDF terms and conditions of support
- Management (NTP, finances, drugs)
- Estimation of drug needs for next year
- Follow-up on previous recommendations

→ Report to the GDF Secretariat → External auditor →
Technical Review Committee for problems

GDF Facts and Figures (Oct 2006)

- Patient treatments supplied: **6.3 million** (grants), **2.8 million** (Direct Procurement Service)
- Grants to date: **US\$ 95 million**
- Direct Procurement Service to date: **US\$ 43 million**
- Total number of countries that have received drugs: **71**
- Average cost to treat a TB patient: **US\$ 14-18**

GDF – some advantages

- Availability of drugs for many more patients
- Fewer stock-outs of drugs
- Better drug quality
- Improved drug management
- Integration of experience of Stop TB partnership partners / technical assistance

GDF – some challenges

- Funding
- Dependency on Stop TB partnership
- Volume of countries and complexity
- Expansion (pediatrics, patient kits, lab kits)
- How to stop supporting a country
- NTP management capacity in recipient countries
- Technical assistance for drug management

Example: TB drugs in a country in Southern Africa

- MDR-TB: 3.4% of a representative sample of new patients in 1998/99
- Some second-line drugs available for 2001-2004
- Stock-outs (2nd line) in 2004 and Aug 2005 - May 2006
- 2005/2006: Mismanagement and stock-outs of streptomycin
- Recent regimen changes from ethambutol (6EH) to rifampicin (4RH)
- Inefficient program supervision

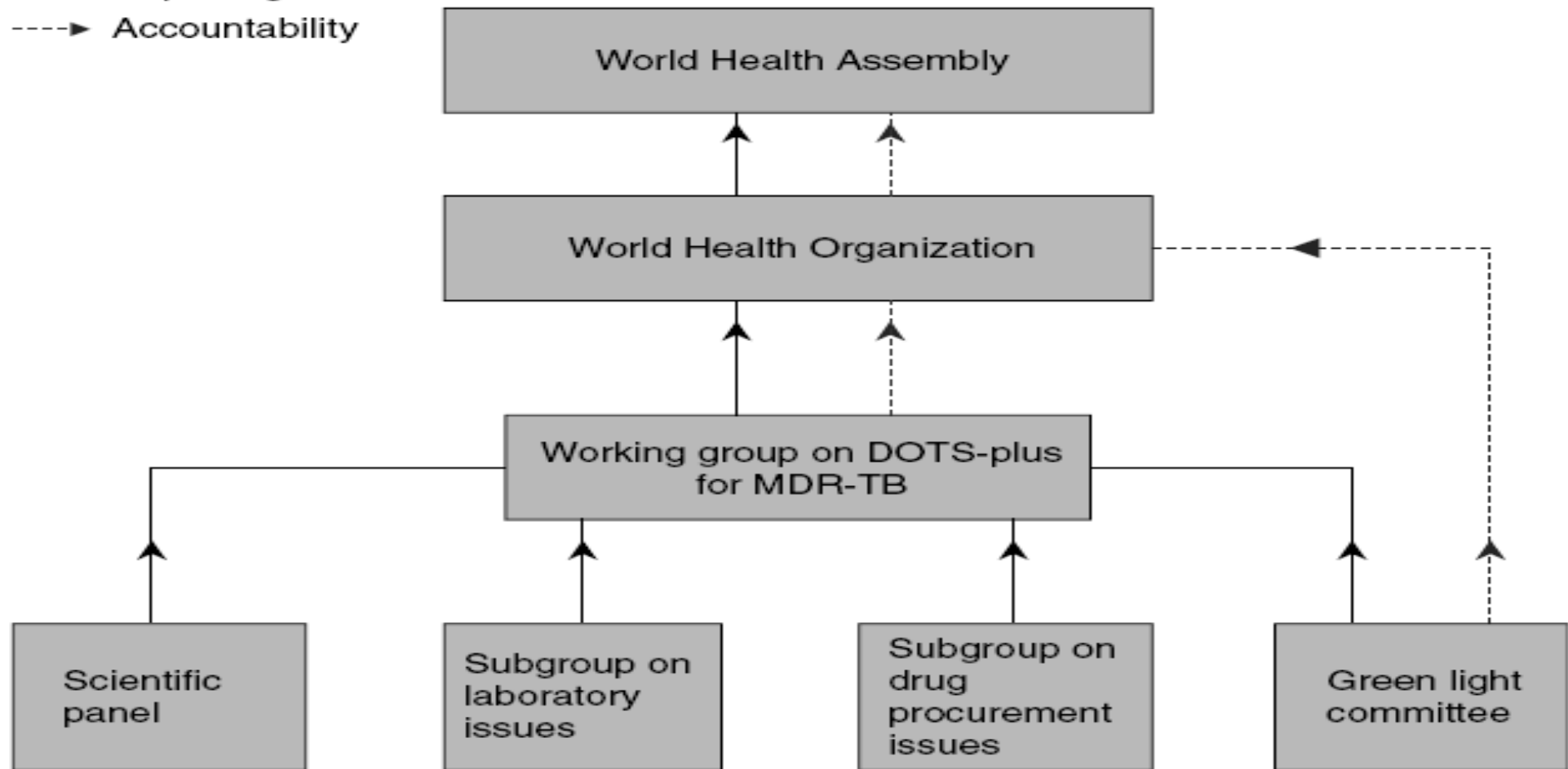
→ Production of MDR

What is DOTS-Plus?

- Expansion of DOTS for MDR-TB
- Aims to manage MDR-TB in mid and low-income countries
- Only for areas with good TB control (basic DOTS):
 - less than 10% defaulters + transfers
 - assured supply of first-line TB drugs
 - DOT in 90% of cases

GLC and DOTS-Plus Working Group

—▶ Reporting
- - -▶ Accountability



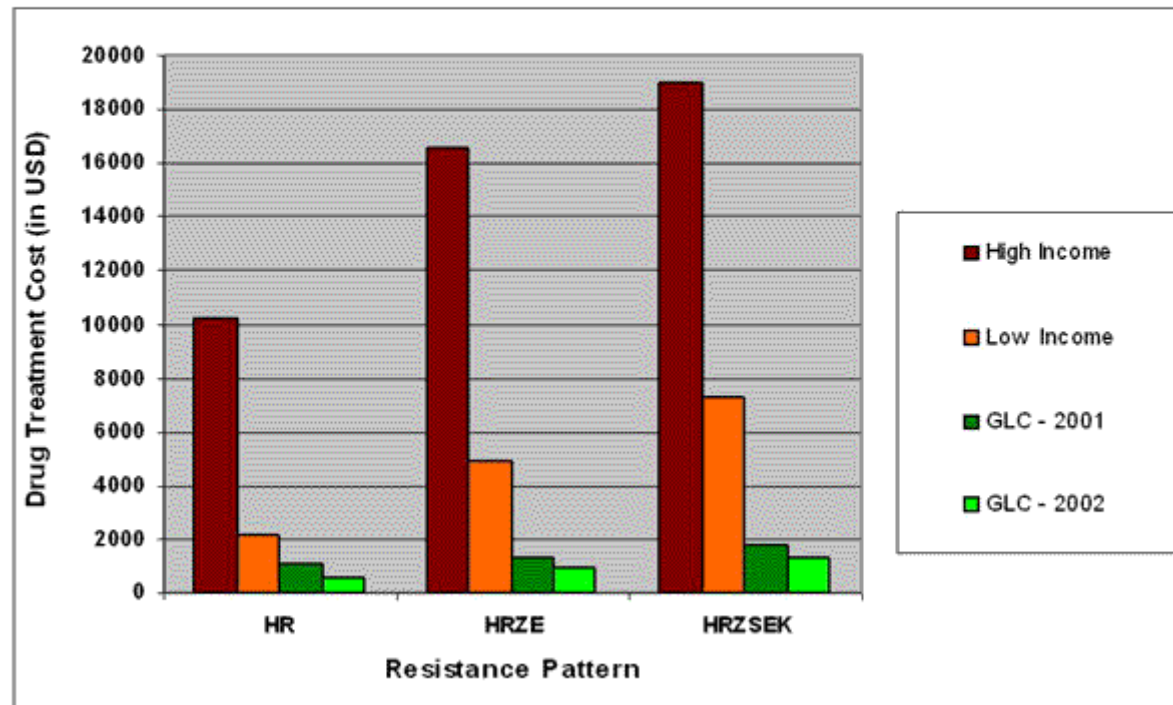
GLC and second-line TB drugs

„Decreasing costs and increasing access“

- selection
- pooled procurement / single client
- mutual interest in preserving the drugs

Science 2001;293;1049-51

MDR-TB Treatment Regimen Costs



GLC – some advantages

- Standardization of use of 2nd line drugs
- GFATM: drugs only through GLC procedures
- Technical assistance provided
- Low prices

GLC – some challenges

- “Countries would buy 2nd-line drugs anyway”
- Impossible to avoid emergence of resistance
- Diversion of resources from DOTS?

**Millennium Development Goal,
Target and Indicators relevant
to TB**

Millennium Development Goal 6

Combat HIV/AIDS, malaria and other diseases

Target 8

To have halted by 2015 and begun to reverse the incidence of malaria and other major diseases

Indicator 23

Prevalence and death rates associated with tuberculosis

Indicator 24

Proportion of tuberculosis cases detected and cured under DOTS

Stop TB Partnership Targets

1990 prevalence rate
halved by 2015

.....
Incidence rate in decline
by 2015

to measure the change in burden, though it should be borne in mind that such surveys are costly and logistically complex.

.....
1990 mortality rate
halved by 2015

→ more indicators → prevalence surveys →

→ more international funding and national human resources

Components of the Stop TB Strategy 2006-2015

1. Pursue high-quality DOTS expansion and enhancement
2. Address TB/HIV and MDR-TB and other special challenges
3. Contribute to health system strengthening
4. Engage all care providers
5. Empower people with TB, and communities
6. Enable and promote research

Stop TB Strategy 2006-2015

2. Address TB/HIV, MDR-TB and other challenges

- a. Implement collaborative TB/HIV activities
- b. Prevent and control MDR-TB
- c. Address prisoners, refugees and other high-risk groups and situations

Budget of Global Plan 2006-2015

- Total required funds: 56.1 billion \$
- Country activities: 44.3 bi \$
- International agencies: 2.9 bi \$
- R&D of new tools: 9 bi \$

- Total available funds: 25.3 bi \$
- → Funding gap 30.8 bi \$

International aid for TB and HIV

- Necessary
- Limited absorption capacity
- Different priorities → competition for attention, changes of strategy
- In-country brain drain
- Paper work
- Lack of concerted action
- Destabilizing effect of big money