The Green Light Committee

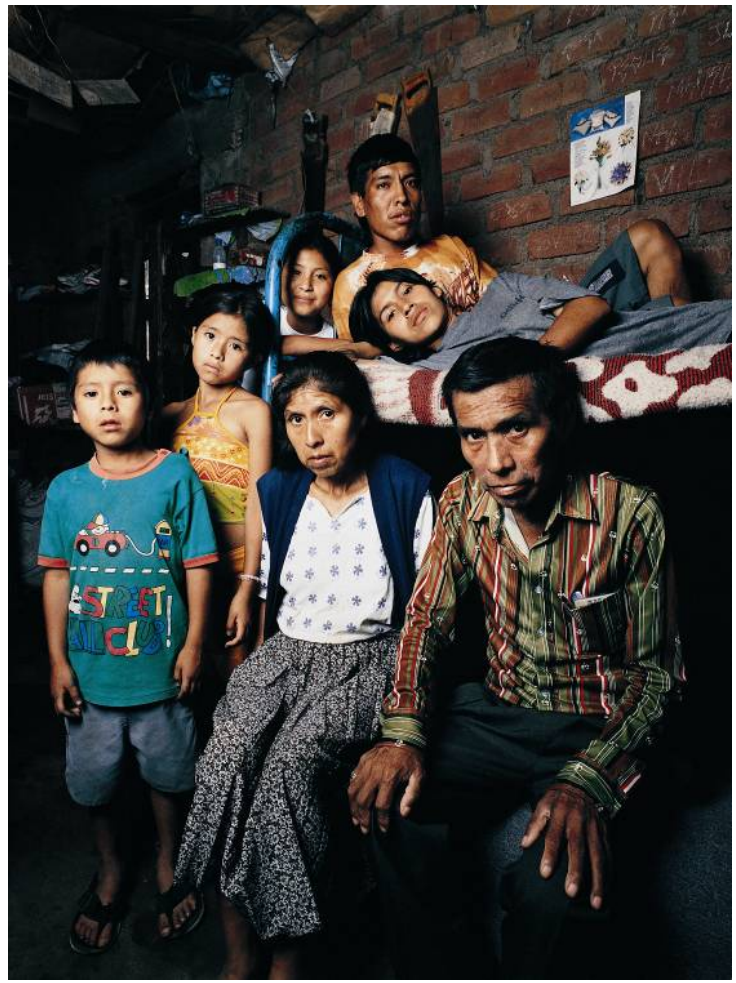
Ensuring access to life-saving treatment for MDR-TB patients while preserving the efficacy of second-line drugs – our last line of defence against TB

Second MDR-TB Consultant Course
Riga, Latvia, 13-17 November 2006

World Health Organization

Rationale for the GLC

- 425,000 MDR-TB cases emerge every year
- Without treatment MDR-TB continues to spread leading to additional suffering for patient and communities
- With inadequate treatment or treatment with poor quality drugs incurable TB strains can develop and spread



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HISTORY

- **1994** Global drug resistance surveillance project launched
- **1999** Stop TB Working Group on DOTS-Plus for MDR-TB
- **1999** Negotiations with pharmaceutical industries
- **2000** Green Light Committee
- **2000** First DOTS-Plus project launched
- **2002** Global Fund decides that all MDR-TB drugs should go through the GLC to ensure efficacy of drugs
- **2005** MDR-TB control proven feasible and cost-effective
- **2002-2006** Rapid scale-up on countries working with the GLC
- **2006** WHO MDR-TB guidelines, Global Plan to Stop TB, new Stop TB Strategy, UNITAID, International Standards of TB care

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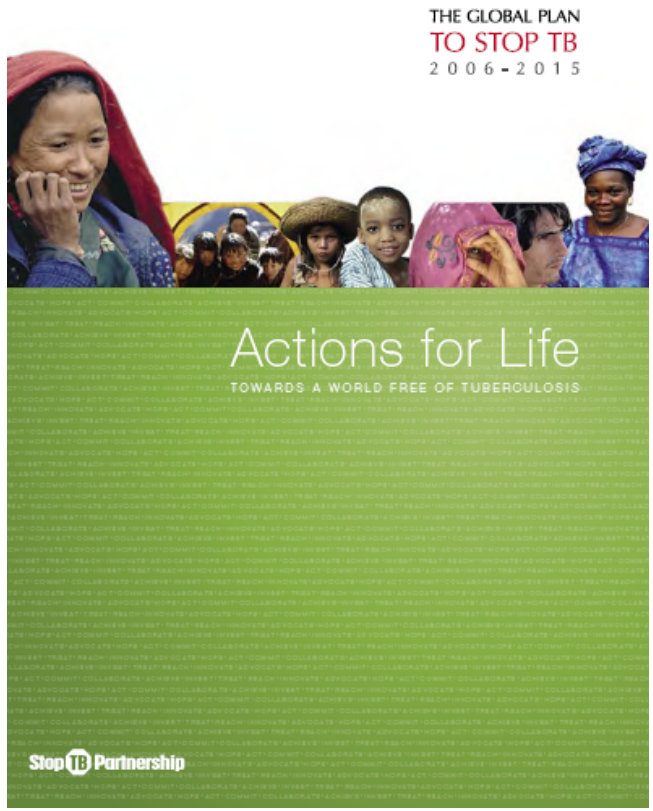
Future

- Major scale-up in access to second-line drugs in low-income countries – reaching TB goals as set fourth in the Global Plan to Stop TB, 2006-2015
- Stabilization in second-line drug market
- Further price reductions of prequalified second-line drugs



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Values of the Green Light Committee

Multi-institutional partnership that:

- Promotes access to quality-assured life-saving second-line drugs at reduced cost for MDR-TB treatment
- Ensures and monitors rational use of second-line drugs
- Protects against XDR-TB and incurable TB

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Green Light Committee

- **Members**: WHO, CDC, IUATLD, Latvia/Estonia NTPs, University of Harvard, Medical Research Council (South Africa). Former members include MSF, KNCV and Peru NTP. New members include KNCV, Hospital Muniz (Argentina) and World Care Council.

- **Task**: To review project applications and determine if projects are in compliance with WHO guidelines. Projects that meet the requirements will benefit from reduced-priced 2nd line drugs and technical assistance.

- **Goal**:
  - Increase access to quality-assured second-line drugs in resource-limited countries

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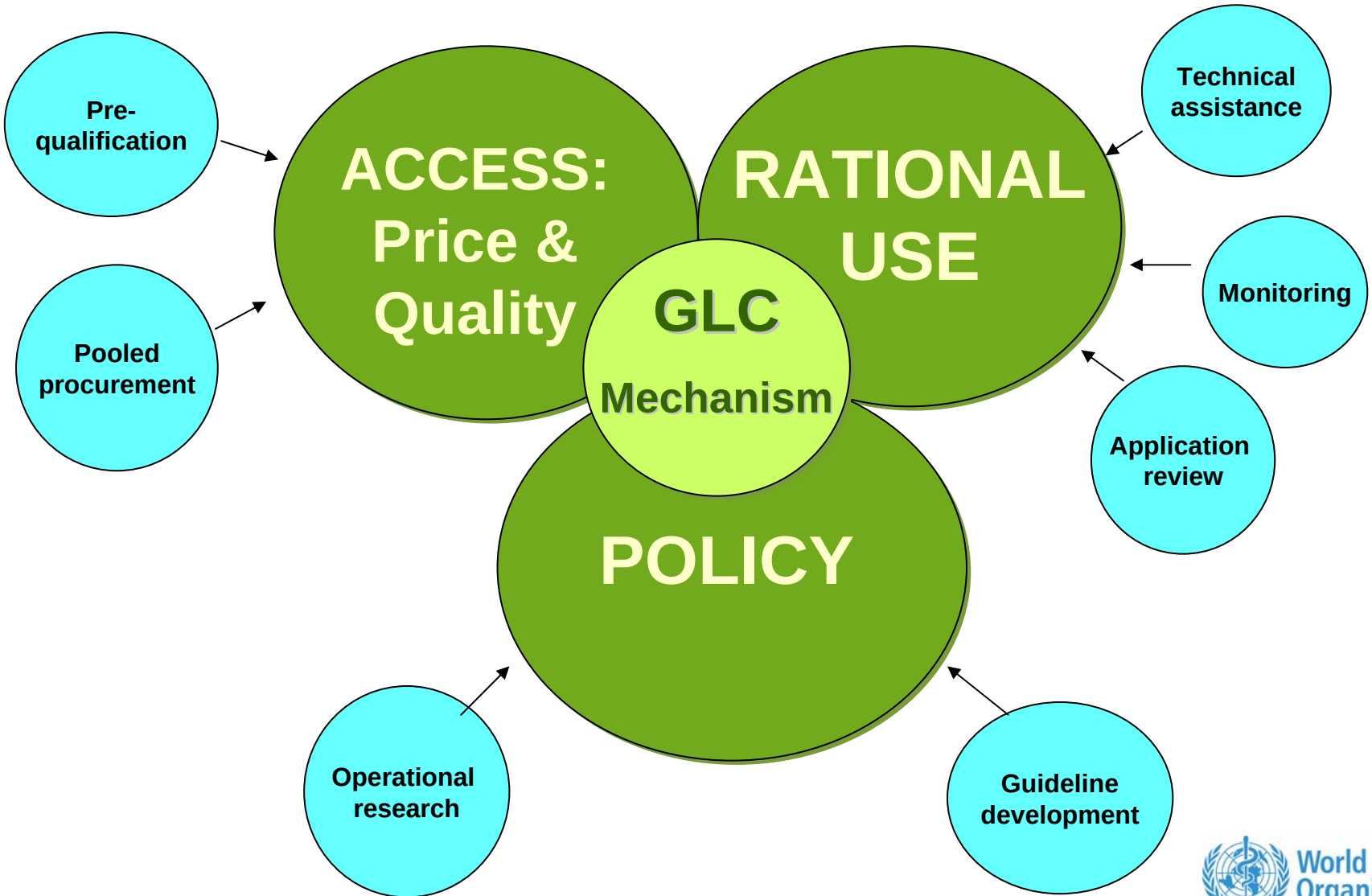
The GLC mechanism



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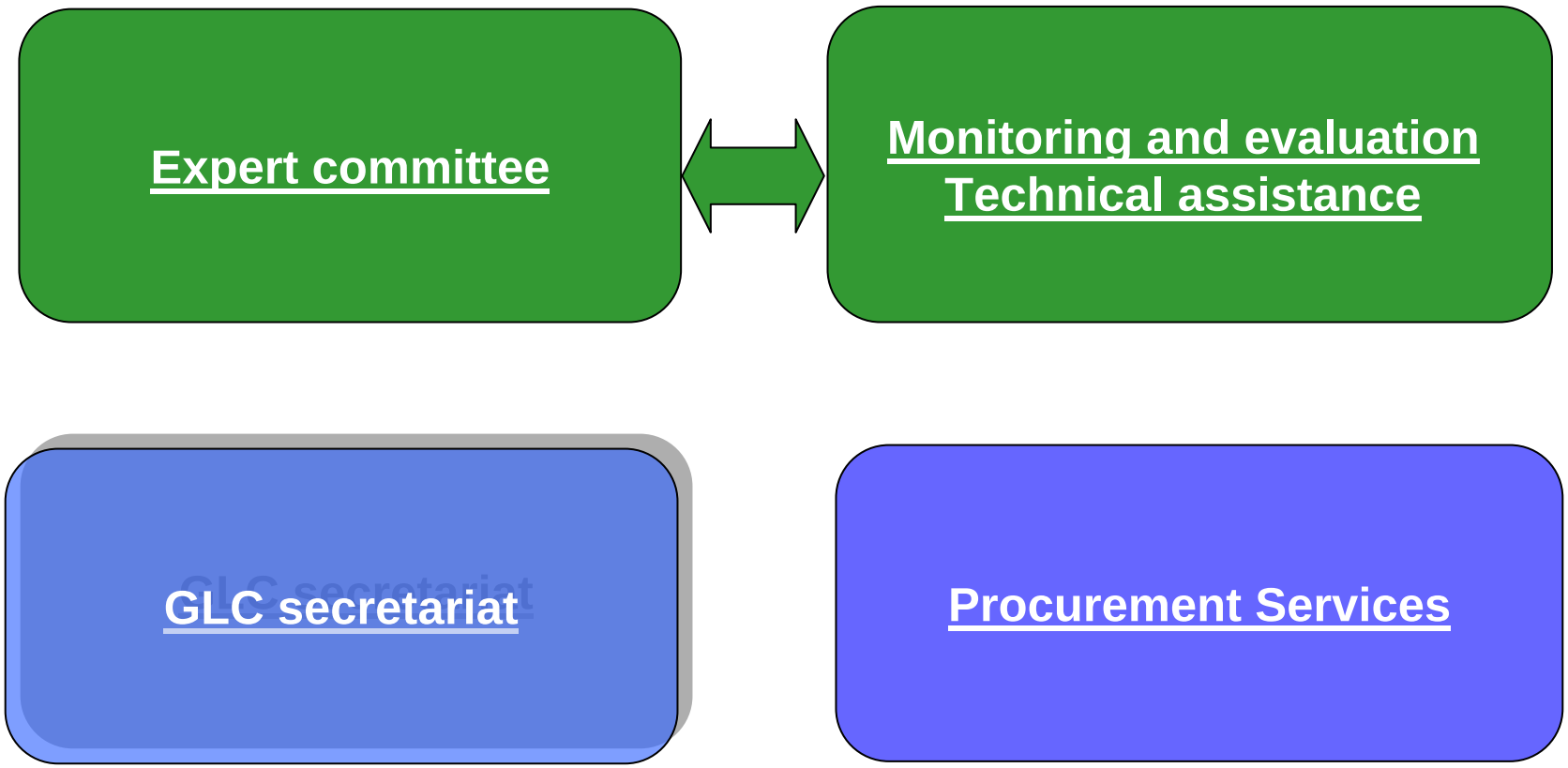
GLC model*: components



*Gupta R, Irwin A, Raviglione MC, Kim JY Lancet 2004;363: 320-324

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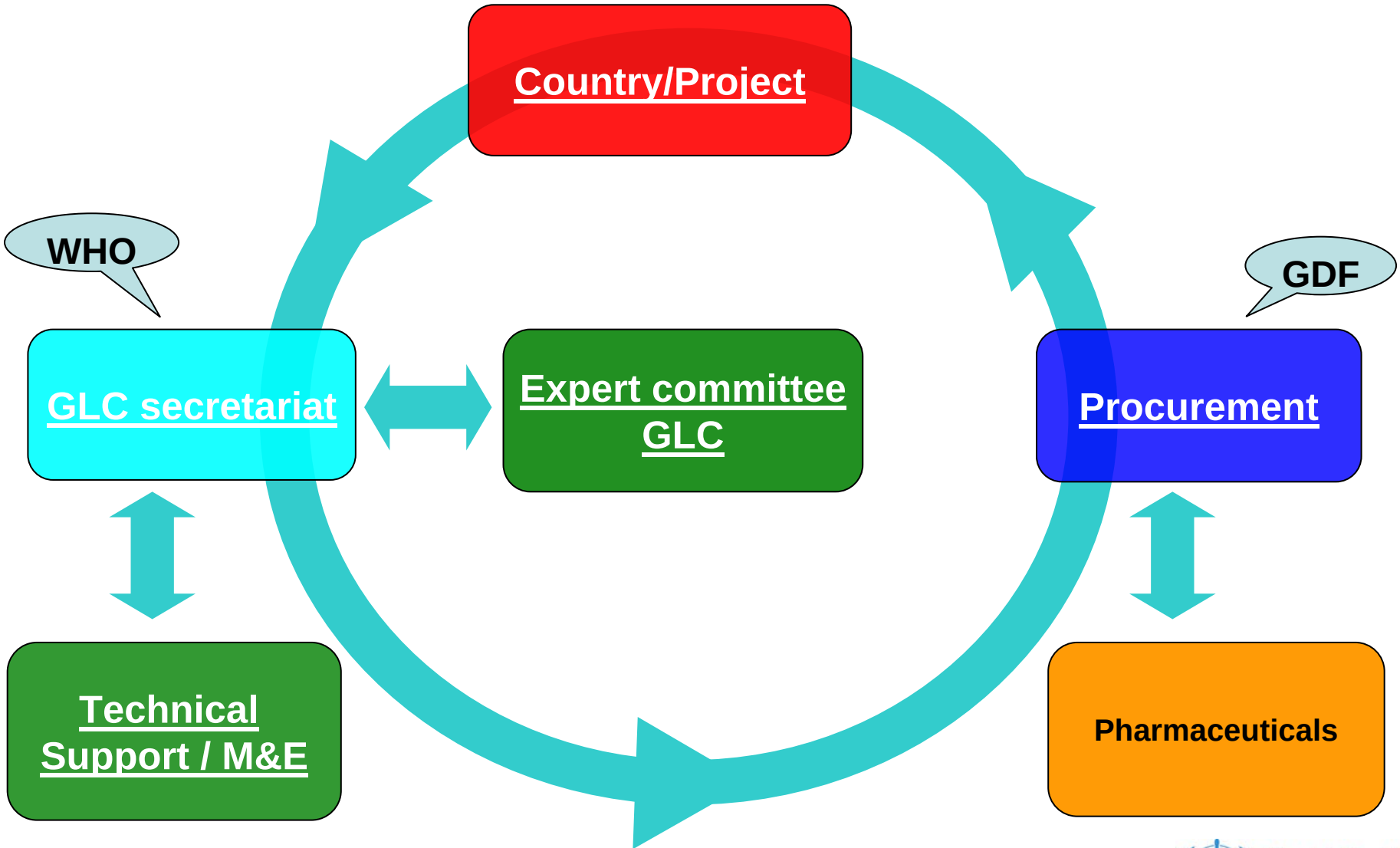
GLC model : action cycle



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Advantages to work with the GLC

- Access to
  - **quality-assured drugs**
  - **low-cost drugs**
  - **continuous drug supply**
  - **technical assistance**
- Increased rational use of drugs
- Creation of wide evidence base for policy development

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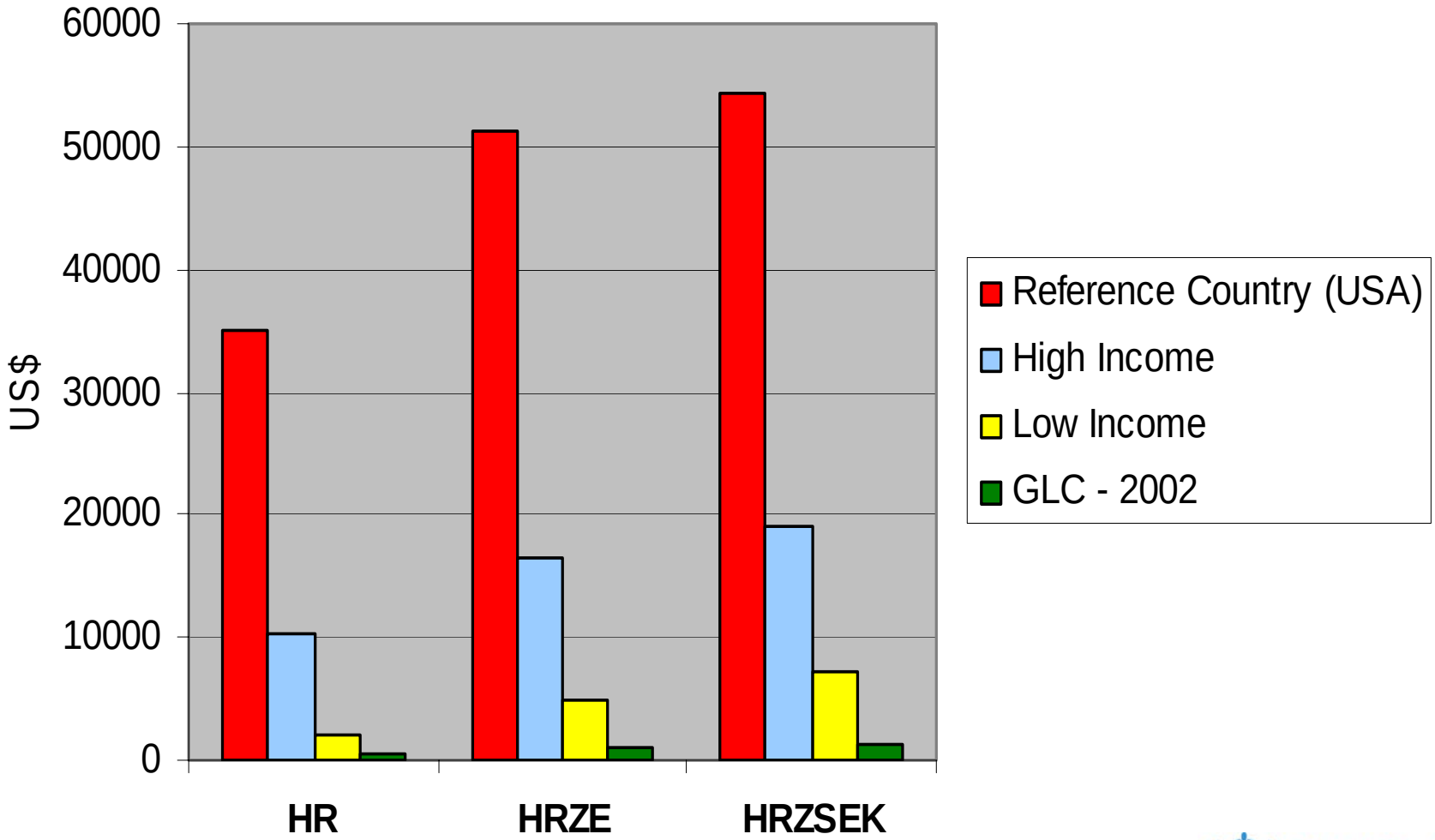
Reduced prices of second-line TB drugs



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Collaboration with the GFATM

"To help contain resistance to second-line anti-TB drugs and consistent with the policies of other international funding sources, all procurement of medications to treat MDR-TB must be conducted through the Green Light Committee (GLC)"

Third Board Meeting, 10-11 October, 2002

"The board reaffirms its decision taken at its Third Board Meeting…

The Board decides that applicants… must include a cost-sharing element for Green Light Committee services. To limit transaction costs this will be defined by the secretariat in consultation with the Green Light Committee as a flat rate per grant per year that will not exceed US 50,000$ per grant per year. "

Thirteenth Board Meeting, 27-28 April, 2006

The Global Fund to Fight AIDS, Tuberculosis and Malaria

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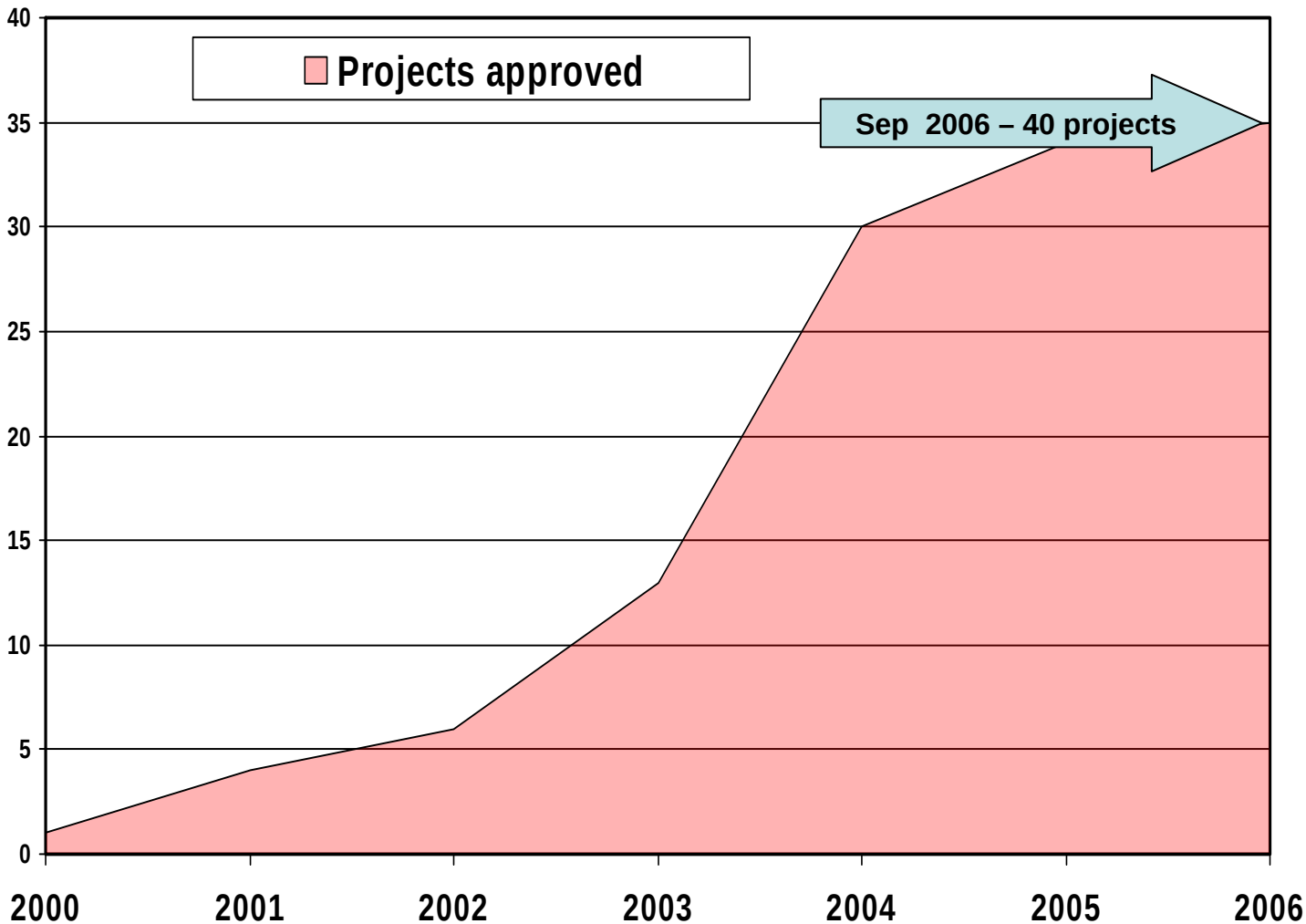
Scaling up of MDR-TB treatment through the GLC



Almost 23'000 patients approved for enrolment

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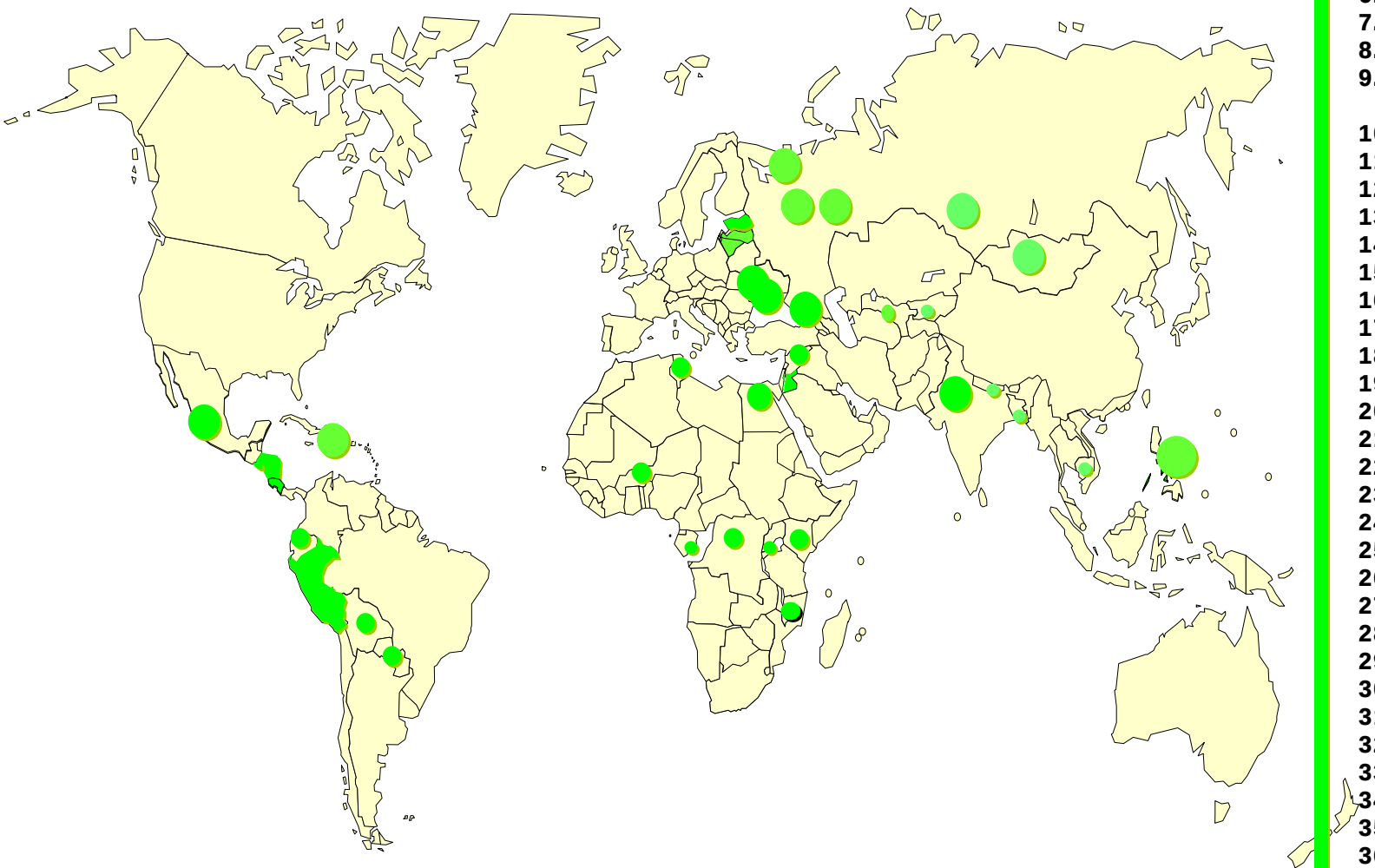
WHO-GLC approved projects by September 2006



GLC-approved projects – 40 countries

1. Azerbaijan
2. Armenia
3. Belize
4. Bangladesh
5. Bolivia
6. Burkina Faso
7. Cambodia
8. Costa Rica
9. Dominican Republic
10. DR Congo
11. Ecuador
12. Egypt
13. El Salvador
14. Estonia
15. Georgia
16. Guinea
17. Haiti
18. Honduras
19. India
20. Jordan
21. Kenya
22. Kyrgyzstan
23. Latvia
24. Lebanon
25. Lithuania
26. Mexico
27. Moldova
28. Mongolia
29. Nepal
30. Nicaragua
31. Paraguay
32. Peru
33. Philippines
34. Romania
35. Russia
36. Rwanda
37. Syria
38. Timor-Leste
39. Tunisia
40. Uzbekistan

GLC approved countries

Total: 40 countries – 22 working with GFATM

- **GFATM support**

- Azerbaijan
- Bangladesh
- Bolivia
- DR Congo
- Dominican Republic
- Ecuador
- Egypt
- Georgia
- Honduras
- Kenya
- Kyrgyzstan
- Mongolia
- Moldova
- Nicaragua
- Peru
- Philippines
- Paraguay
- Romania
- Russia
- El Salvador
- Timor-Leste
- Uzbekistan

- **Domestic or other donor support**

- Armenia
- Belize
- Burkina Faso
- Costa Rica
- Estonia
- Guinea
- Haiti
- India
- Jordan
- Cambodia
- Lebanon
- Lithuania
- Latvia
- Mexico
- Nepal
- Rwanda
- Syria
- Tunisia

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Sequence of events

Requirements outlined in the Guidelines are in place

DR-TB situation is well defined

Laboratory provides sufficient capacity and quality

Small projects may utilise services of the external laboratory

Key stakeholders of the project identified

Project protocols prepared including:
- Treatment strategy
- R&R system
- Training plan
- Drug management plan
- Lab quality assurance
- Social support

Application to GLC – review and approval

Drug procurement using GLC mechanism for quality assured, preferentially priced drugs

Project implementation

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Timing of GLC application

- **Based on “Instructions” and follow principles outlined in the “Guidelines”**
- **Not necessary to be submitted with GFATM proposal, but…**
- **Preparation has to start well before the planned initiation of MDR-TB patients enrollment (factoring application writing, GLC review, procurement lead times, importation)**
- **Baseline situation very important, incremental approach vs. whole country projects.**

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