World Health Organization

Stop TB Partnership

ANNUAL REPORT 2008

Green Light Committee Initiative
of the Working Group on MDR-TB
of the Stop TB Partnership

Green Light Committee (GLC) of the
Working Group on MDR-TB
STOP TB PARTNERSHIP
Secretariat housed at WHO Geneva

US Centers for Disease Control and Prevention, Partners in Health (Harvard Medical School), International Union against Tuberculosis and Lung Diseases, National Tuberculosis Programme Latvia, KNCV Tuberculosis Foundation, Médecins Sans Frontières, Hospital Muniz, World Care Council and World Health Organization

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MESSAGE FROM THE CHAIR

Since its inception in 2000, the Green Light Committee (GLC) Initiative has worked to ensure that patients receive appropriate treatment for drug-resistant tuberculosis (DR-TB) with quality-assured second-line anti-TB drugs (SLD) in programmatic settings that prevent the emergence of further drug resistance. By December 2008, the GLC had approved almost 50,000 patient treatments in 93 programmes/projects spanning 60 countries.

In April 2009, the Government of the People's Republic of China and the World Health Organization (WHO) hosted Ministers of Health from the 27 high-multidrug-resistant tuberculosis (MDR-TB) burden countries (plus six additional countries) at a meeting in Beijing. The participating nations unanimously endorsed a declaration calling for rapid scale-up of high-quality MDR-TB treatment globally, and pledged to move their own countries towards universal access. This meeting was followed in May 2009 by a WHO World Health Assembly resolution calling for universal access to diagnosis and treatment of MDR-TB and extensively drug-resistant tuberculosis (XDR-TB). The resolution called on WHO "to provide support to Member States in developing and implementing strategies to engage all relevant public, voluntary, corporate and private health-care providers in the training for and scaling up of prevention and control of tuberculosis including MDR-TB and XDR-TB and all aspects of tuberculosis-HIV coinfection." This included the request "to strengthen the Green Light Committee mechanism to help to expand access to concessionally-priced and quality-assured first- and second-line medicines."

As we look to a future with universal access to MDR-TB treatment, we face a number of important challenges. The first challenge is the need to rapidly diagnose all forms of DR-TB. Since the beginning of 2008, the GLC Initiative has been working in close collaboration with the Global Laboratory Initiative (GLI) to build appropriate diagnostic capacity in countries. The GLI is on track to diagnose more than 130,000 DR-TB patients by 2011. The second major challenge is the need to ensure access to concessionally-priced quality-assured SLD medications. Much is happening through the Global Drug Facility (GDF), in partnership with WHO Prequalification and industry; more work will be needed in this area in order to reach the anticipated global demand.

The third major challenge is in the area of program implementation. With innovative funding mechanisms such as the Global Fund to fight AIDS, Tuberculosis, and Malaria (GFATM) and UNITAID, the task now is to build country-level capacity to make universal high-quality treatment of DR-TB a reality. The Fourth Global Drug-resistance Surveillance Report, released in February 2008, clearly showed a problem that has grown beyond a hospital-based solution. The sheer volume of DR-TB patients now requires innovative approaches that extend into ambulatory networks and even directly into patient communities. Numerous models exist — from Nepal to Georgia, and from Pakistan to Lesotho — with proven track records. These lessons need to be shared widely and adapted as necessary.

On behalf of the GLC I want to thank the many partners who are deeply engaged in making universal access to DR-TB treatment a reality. We look forward to our continued work together.

Salmaan Keshavjee
MD, PhD
Chair, Green Light Committee

Message from the GLC Secretariat

The GLC has played a central role in the global response to MDR-TB since its early days in 2000. It has proved that in combination with effective monitoring and evaluation, availability of quality assured (QA), second line drugs (SLDs), as well as technical assistance, MDR-TB can be successfully managed under programmatic conditions in low-income settings. The GLC successfully continues to implement its mandate in partnership with the GFATM, UNITAID, GDF, the WHO Prequalification programme, pharmaceutical manufacturers, and other partner institutions in the GLC Initiative. Today the GLC is recognized as a quality stamp for any DR-TB programme/project by governments and the funding agencies.

What are the future expectations of the GLC mechanism? The ministerial meeting of high burden MDR-TB countries organized in Beijing in April 2009 as well as the following World Health Assembly (WHA) resolution that was adopted in May 2009 both confirm that countries see the GLC as the mechanism to help expand access to concessionally-priced and quality-assured medicines and to encourage and assist local pharmaceutical manufacturers in high-burden countries to get qualification within the GLC mechanism. Both the ministerial meeting declaration and the WHA resolution call for strengthening of the GLC to empower it for this important task. The challenges ahead of the GLC are substantial, including the diversification of technical assistance services and ensuring the availability of SLDs to meet the growing needs of countries.

I am confident that WHO as the host of the GLC Secretariat will extend the necessary support to the GLC Initiative in addressing the above challenges and in fulfilment of its essential role to help countries meet the scale-up goals for DR-TB treatment. I would also like to take this opportunity to thank the funding agencies and encourage them to ensure sufficient funding for countries to implement the MDR-TB response plan.

Dr Wieslaw Jakubowiak,
GLC Secretariat
Team Leader
WHO/HQ/STB/THD

TABLE OF CONTENTS

EXECUTIVE SUMMARY

In 2008, the GLC Initiative saw a substantial increase in activity: a 36% rise in the number of applications reviewed and 54% increase in approved patients if compared to average numbers in 2006 and 2007. With the help of strategic partners like the Global Fund, UNITAID, PEPFAR and Eli Lilly, initially approved country projects with small patient cohorts have started evolving into national programmes for treatment of drug-resistant tuberculosis (DR-TB). This positive trend is expected to continue, especially with the support of initiatives such as the Global Laboratory Initiative and growing commitment from countries.

The GLC Initiative continues to provide support to countries through technical assistance and monitoring/evaluation to continuously ensure that a high standard of treatment is provided to patients. The technical assistance services have been diversified to assist countries at different stages of their interaction with the GLC Initiative, including pre-application assistance and pre-approval assessments.

The availability of high quality SLDs to the GLC-approved programmes/projects remains of paramount importance for the GLC Initiative and for the countries to maintain the high quality of services and to succeed in effectively treating patients. Although we have seen the increase of 58% in the value of the orders placed for second-line medicines in 2008 over those purchased in 2007, there are still several challenges to address and ensure expected scale-up in the GLC approved programmes/projects. Ensuring availability and production capacity of some of the second-line drugs, increasing the number of prequalified products, strengthening the product supply chain and effectively assisting countries in resolving bottlenecks for product registration and importation are examples of issues that will require particular attention and further efforts by all partners in the GLC Initiative in 2009 and beyond.

Over 2008 the GLC has continued to revise and streamline its procedures and rules that guide the application review process and allow the Committee to respond efficiently to the increasing demand for its services.

None of the achievements of the GLC Initiative in 2008 would have been possible without the involvement of the technical partner organizations with their global reach to countries in need and affected patients. We would like to praise the dedicated work of all the consultants, a strong network of highly competent and motivated individuals who help the Initiative to provide its services to countries. Last but not the least we would like to thank the major donors of the GLC Initiative: PEPFAR, UNITAID, the Global Fund and Eli Lilly for their generous and continuous support to the Initiative. We count on our continued collaboration in the next years to provide life-saving treatment to DR-TB patients around the world.

INTRODUCTION

Diagnostic cultures for MDR-TB suspects.

The global response to multidrug-resistant tuberculosis (MDR-TB) and extensively drug resistant (XDR-TB), embedded in the Global Plan to Stop TB 2006-2015 [1], sets a target of achieving universal access to diagnosis and treatment of MDR-TB by 2015. To meet the targets set in the Global Plan, diagnosis and treatment of MDR-TB must be rapidly scaled up. Effective programmatic management of drug-resistant TB is a complex undertaking, requiring financial resources, laboratory and hospital infrastructure, and technical expertise,. Compliance with international standards of care is vital as treatment with improper regimens of second-line drugs (SLD) risks amplifying and spreading MDR and XDR-TB even further.

The Working Group on DOTS-Plus for MDR-TB (currently the Stop TB Partnership Working Group on MDR-TB) was established in 1999 to lead the global effort to control MDR-TB. This working group formed the Green Light Committee (GLC) in 2000 to provide technical assistance to DOTS programmes/projects, promote rational use of second-line anti-TB drugs (SLD) worldwide and improve access to concessionally-priced, quality-assured SLDs.

The 2008 emergency update of the WHO Guidelines for the Programmatic Management of Drug- Resistant Tuberculosis (WHO Guidelines) [2] provides recommendations for appropriate management of DR-TB to avoid generating further drug resistance and to take into consideration the value of community-based and patient-centered care. The GLC has developed a mechanism to assist countries in adapting the framework described in these WHO Guidelines to

[1] http://www.stoptb.org/globalplan/

[2] http://www.who.int/tb/publications/2008/programmatic_guidelines_for_mdrtb/en/index.html

country-specific contexts. Countries that meet the framework requirements, with a strong DOTS foundation and a solid plan to manage DR-TB, can benefit from quality-assured SLDs at reduced prices. The GLC also offers technical assistance before implementation of programmes/projects for control of DR-TB and monitors approved programmes/projects.

Today the GLC forms part of the Green Light Committee Initiative ("GLC Initiative"), a mechanism that:

- establishes compliance of country MDR-TB programmes/projects with the WHO Guidelines and other international standards set in the field of tuberculosis (TB) care and control;
- enables access to affordable, high-quality SLDs for the treatment of MDR-TB;
- provides monitoring and technical assistance to countries in scaling up their MDR-TB programmes/projects; and
- advises WHO on policy-related matters to effectively prevent and control MDR-TB based on the best available scientific evidence.

The core of the GLC Initiative is composed of the GLC, the Secretariat, and the Global Drug Facility (GDF).

The Green Light Committee (GLC) provides the following services:

- expert technical review of applications;
- evaluation of proposed programmes/projects;
- assessing and determining training and technical assistance needs; and
- contributing to the evidence base for the programmatic management of DR-TB.

The Initiative is coordinated by the **GLC Secretariat,** which is hosted and administered by the WHO.

The Global Drug Facility **(GDF)** is the procurement arm of the GLC Initiative, with the GDF Secretariat housed at WHO, which, together with its procurement agent, coordinates and implements drug order processes for GLC approved programmes/projects.

WHO and its technical partners provide technical assistance to GLC-approved MDR-TB programs including the following:

- pre-application assistance with DR-TB programme/project development and needs assessment;
- compulsory regular monitoring of approved programmes/projects; and
- peer support and knowledge sharing with other GLC-approved programmes/projects.

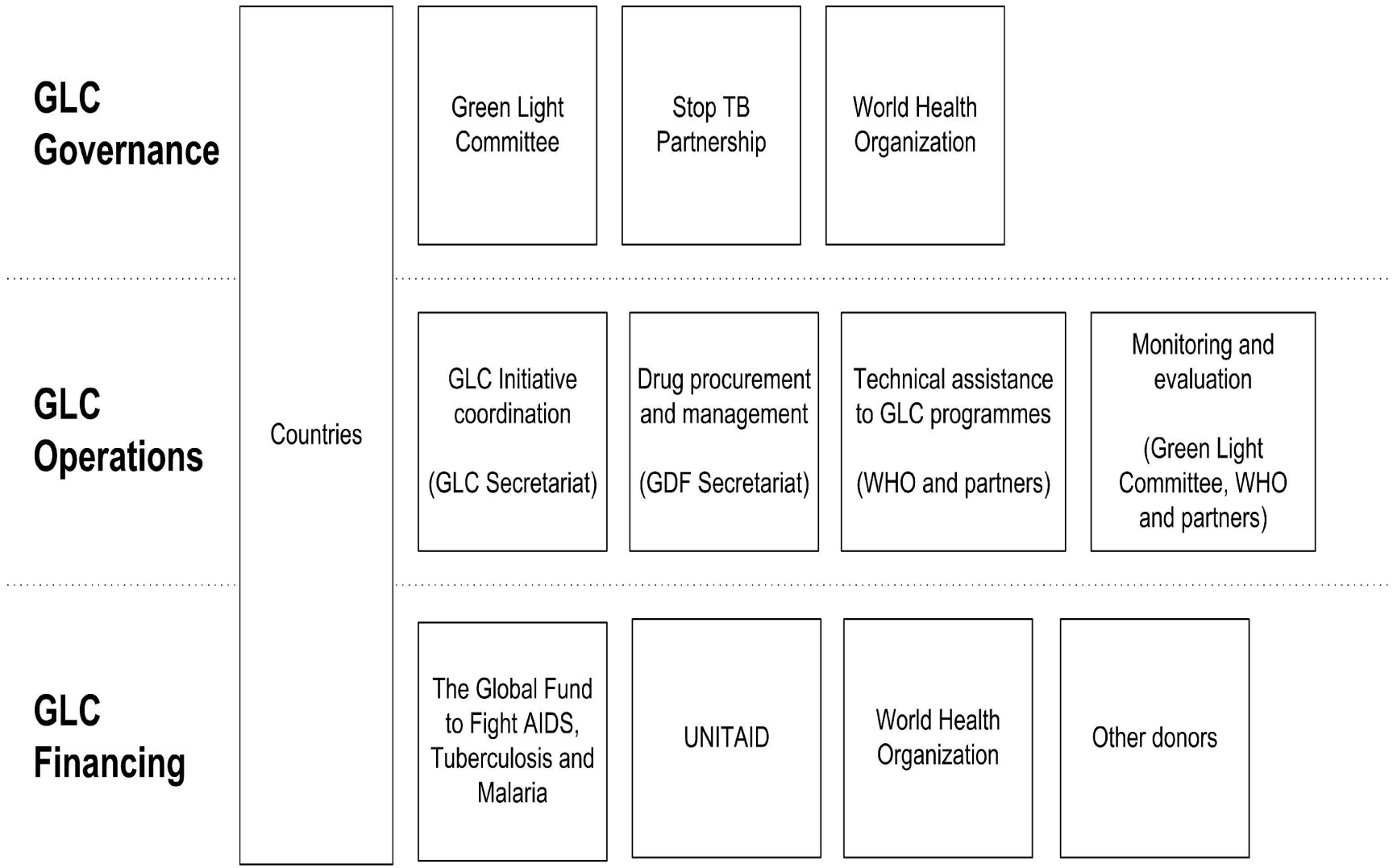


Diagram 1: The GLC Initiative

COMMITTEE MEMBERSHIP

GLC Members at the 54th GLC meeting in Montreux, Switzerland.
From Left to Right - Front: Dr Salmaan Keshavjee (PIH), Dr Timothy Holtz (CDC), Dr Myriam Henkens (MSF), Dr Agnes Gebhard (KNCV), Dr Wieslaw Jakubowiak (WHO) - Back: Dr Domingo Palmero (Hospital Muniz), Dr Fuad Mirzayev (WHO), Dr Jacques van den Broek (KNCV). Missing: Case Gordon (World Care Council)

The GLC consists of nine member institutions that are drawn from the Stop TB Partnership Working Group on MDR-TB (WG on MDR-TB) and chosen based on a competitive selection process. The member institutions have a demonstrated leadership in public health and are active in TB care and control internationally. Each member institution is represented by two experts in programmatic, scientific, clinical, and microbiological aspects of TB, with particular focus on DR-TB, who serve WHO in an advisory capacity. The GLC freely consults outside experts as needed. There have been no changes in the Committee membership during 2008.

M

GLC members perform the following functions:

- Review applications to the GLC and monitoring and evaluation reports, both as a primary (in-depth) reviewer and as part of the committee review process.
- Participate in GLC discussions and decisions regarding all applications and other GLC matters, including face-to-face meetings, paper-based correspondence, and electronic telecommunications (teleconference, email, internet).

- Attend all GLC meetings and participate in all GLC decisions. If attendance by the principal representative is not possible, the institution's alternate member should attend.
- Make recommendations to WHO on specific instructions to programs interested in applying to the GLC.
- Conduct pre-assessment of programs and promote technical assistance to potential and approved programs.
- Improve GLC processes by contributing to GLC-related policies and procedures regarding application reviews, country visits and report writing.
- If necessary, individual GLC members may seek outside expert advice; however, external input must be agreed to by the designated GLC member institution and channeled through the formal representative (principal or alternate).
- Actively promote and advocate for the mission and objectives of the GLC Initiative at Partnership forums, conferences, scientific symposia and in meetings with potential or already approved GLC programmes/projects.

All members are required to adhere to rules of conflict of interest and confidentiality and, thus, cannot participate in the decision-making on applications from programmes/projects in relation to which they have or had a direct or perceived conflict of interest.

Future membership

During its 50th meeting that took place in August 2008, the GLC initiated a discussion on the possible models for its membership rotation, taking into account that in April 2011 all of the institutional members, except MSF, will expire (2 years initial membership and 2 years of possible extension). The Committee proposed a staggered approach for the turnover of its member institutions, clearly recognizing that the work of the GLC is impossible without sufficient representation of the large key WHO partner organizations that have broad reach in affected countries, and strong technical expertise.

At the same time the GLC recognized the need to keep its membership open and competitive, especially to allow new smaller organizations a chance of being represented on the Committee. It was decided that a way of mentoring the newcomer member organizations should be worked into the rotation plan.

As of December 2008, members of the GLC included (principal member listed first):

Partners In Health (PIH) -
Salmaan Keshavjee - Chair
Jaime Bayona

KNCV Tuberculosis Foundation
Agnes Gebhard
Jacques van den Broek

International Union Against Tuberculosis & Lung Disease (IUATLD)
Jose Caminero
Arnaud Trebucq

Hospital General de "Francisco J. Muniz"
Domingo Palmero
Cristina Brian

U.S. Centers for Disease Control and Prevention (CDC)
Timothy Holtz
Charles Daley

State Agency for TB & Lung Disease, Latvia
Vaira Leimane
Gunta Dravniece

Médecins sans Frontières (MSF)
Myriam Henkens
Juliet Melzer

World Care Council (WCC)
Case Gordon

World Health Organization (WHO)
standing member
Fuad Mirzayev
Matteo Zignol


Photo: M. Pavelsons

GLC ACTIVITIES IN 2008

In 2008, the GLC held 6 meetings. The 49th and 52nd meetings were held via teleconference. The 47th and 48th GLC meetings were held in person and hosted by the WHO, in Geneva and Montreux, Switzerland, respectively. The 50th GLC meeting took place in The Hague, Netherlands and was hosted by the KNCV Tuberculosis Foundation. The 51st GLC meeting was organized and hosted by Médecins Sans Frontières in Paris, France.

In accordance with the set of services that the GLC provides, its performed core activities in 2008 were related to the:

- review of applications
- monitoring and evaluation of GLC approved program sites
- technical assistance to implementing or applying country programs, and
- revision of the Guidelines for the Programmatic Management of Drug-resistant Tuberculosis, which were launched in August 2008.

Apart from these core activities, the GLC launched several initiatives with the goals of assisting regions and countries to build programmatic capacity to manage drug-resistant TB and help resolve major bottlenecks to scaling up treatment of patients with MDR-TB.

These initiatives focused on the following:

- Streamlining monitoring and evaluation of GLC-approved programs;
- Expanding the list of GLC consultants and the services they provide;
- Facilitating the GLC application review process;
- Improving procurement through the GLC mechanism;
- Assisting countries with drug management in collaboration with GDF (for further detail on procurement and drug management activities please refer to the chapter on procurement).

MDR-TB patients receiving treatment in the male ward at the National Institute of Diseases of Chest Hospital (NIDCH) in Dhaka, Bangladesh, a GLC approved project.

GLC Taskforce on Monitoring and Evaluation

A taskforce comprised of GLC members, consultants and WHO experts was set up by the GLC in October 2007 to streamline the monitoring and evaluation function of the GLC.

The objectives of the taskforce were to explore different ways of monitoring the GLC-approved programs and to allow for better knowledge-sharing among the countries and program sites. In addition, the taskforce looked into ways of expanding the current GLC consultant pool and developing an evaluation framework which could serve as a basis for programme/project expansions.

The taskforce continued its function into 2008 and presented the draft GLC Monitoring and Evaluation tool at the 47th GLC meeting. The tool provides a unified format for the GLC monitoring and evaluation reports and introduces additional requirements to describe the programme's/project's plans for scale-up, the available financial resources and the need for technical assistance in order to support the scale-up. In addition, the new monitoring report format reflects the progress towards established targets for those programmes/projects that are supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF). The work on aligning the format of the GLC monitoring and evaluation reports with the GF targets will continue in 2009.

The work of the taskforce has produced tangible results: the GLC monitoring reports now provide an easy, clear at a glance overview of the functioning of the DR-TB component in any GLC approved programme/project. GLC monitoring reports will increasingly provide a full picture evaluation that the GF will be able to use for evaluation of the progress in its respective grants.

The recommendations of the taskforce on expansion of the network of GLC consultants have found reflection in a new approach of engaging and training junior consultants which is described in the next section.

GLC Consultants

In view of the expected scale-up of the approved GLC programmes/projects, the increase in new applications as well as the diversification of the GLC technical assistance services, including pre-application, pre-approval and post-approval technical assistance, the expansion of the pool of experienced GLC consultants is of crucial importance.

During its 47th meeting the GLC endorsed the criteria for selection of the GLC consultants. The criteria draws the line between the GLC consultants and the GLC representatives. In addition to the roles outlined for the GLC consultants, the GLC representatives represent the GLC in programmes/projects that are facing major political, technical or programmatic issues and are appointed from among the GLC members.

All GLC consultants are required to fulfill the following criteria:

- post-graduate degree in Medicine or masters/doctorate degree in a relevant area;

- extensive experience in the programmatic management of MDR-TB; OR
- extensive experience in the programmatic management of TB with some knowledge of MDR-TB: OR extensive experience monitoring and evaluating TB or MDR-TB control programmes/projects;
- knowledge of relevant WHO material on MDR-TB including but not limited to the WHO Guidelines;
- knowledge of GLC requirements;
- completion of the WHO MDR-TB Consultants Training Course; and
- experience in GLC missions and knowledge of GLC requirements and WHO guidelines.

Currently there are 69 GLC consultants specializing in infection control, laboratory aspects, reporting and recording, programmatic and clinical management of DR-TB, drug management, social support and pediatrics. The GLC consultants are distinguished from MDR-TB consultants by the fact that they are authorized to go on formal GLC monitoring missions and provide recommendations on cohort expansion in a GLC approved programme/project.

The GLC Initiative also involves a larger network of 143 MDR-TB consultants covering all geographical regions and capable of working in 22 languages. MDR-TB consultants are engaged in technical assistance missions, including the preapproval and pre-application missions. The requirements for the MDR-TB consultants are the same as for the GLC consultants, except that MDR-TB consultants are not required to have experience in GLC missions and knowledge of GLC requirements.

The GLC Secretariat organized a GLC consultants meeting in Maison de Polytechnicien in Paris, France in October 2008 to update on new procedures and technical issues. The GLC consultants meeting was very well attended by a number of new consultants and members of the Working Group on MDR-TB and the subgroups. The meeting updated the consultants on the new technical issues, forthcoming amendments to the WHO Guidelines, new aspects in operations of the GLC Initiative, new monitoring tools, improved coordination mechanisms with the GLC Secretariat and the collaboration with the Global Laboratory Initiative (GLI).

In December 2008 the GLC Secretariat together with the WHO DR-TB team organized the third DR-TB Consultants' Training Course in Lima, Peru. Twenty five consultants received the necessary training to enable them to participate in GLC monitoring and technical assistance missions.

The GLC is also implementing a new approach whereby the newly trained MDR-TB consultants are encouraged to join experienced GLC consultants on official GLC missions in order to gain the experience necessary to enable them to carry out independent GLC monitoring missions in the future.

GLC Forum

At its 51st meeting, the GLC made a decision to organize a GLC Forum as a

global meeting of key countries managing GLC-approved MDR-TB programmes/projects. The meeting is intended to boost horizontal collaboration, strengthen networking of GLC-approved MDR-TB programmes/projects and accelerate scale-up and technical assistance. The meeting will be combined with one of the 2009 GLC meetings to ensure participation of the whole Committee in the forum. The first GLC Forum is scheduled for the third quarter of the 2009.

Streamlining GLC Application Review

In the last two years the demand for GLC services has more than doubled. To be able to cope with the increased number of applications and shorten the application review time, the GLC *modus operandi* is frequently changed and adjusted. During its 51st meeting the GLC reviewed its Operating Procedures to include the established practice and decisions on procedural matters that the Committee has made over time in its meetings.

The endorsed changes in the Operating Procedures aim to make the **post- GLC meeting clearances** of correspondence to countries swifter, as the GLC Members agree on the minutes of the meeting containing summary recommendations and not the content of each separate letter of correspondence. In case of complicated recommendations the correspondence is cleared with the Chair and the principal reviewers.

The revised Operating procedures establish a **90-day rule** following approval for programmes/projects to place drug orders and respond to the GLC questions. Past this deadline the GLC considers withdrawing its approval or closing the application. This provision seeks to avoid long periods of inactivity on the part of GLC applicants and approved programmes/projects.

It is expected that a number of programmes/projects will be scaling up in the coming years in response to the recent WHA resolution on MDR and XDR-TB care (WHA62.15); in anticipation of this trend, the GLC has fine-tuned its procedures for **expansion applications**.

The current revision provides for a possibility to have expansion applications approved outside of the regular review cycle and regular meeting through the e-mail review procedure, whereby the GLC members are required to send their decision to the Secretariat by e-mail within 7 days time.

The recent revision also introduced a second option for an expansion, whereby the decision to expand a programme/project can be made by the Chair in consultation with the Secretariat, following a recommendation for expansion in the monitoring report and the receipt of an official letter from the applicant where such an expansion is requested.

These two procedural changes can speed up the review process of expansion applications by up to two months, and the adoption of these procedures has already allowed improvements in efficiency of the work of the GLC and its Secretariat in 2008.

In addition, the recent revision included the following changes in GLC procedure:

- In cases of **minor outstanding clarifications** or minor outstanding conditions that need to be met by the applicant before the final decision is made, a programme/project can still receive approval by the Committee under the new procedure. The Secretariat has been empowered to follow up with the country and clear on such minor conditions.

- In cases where the GLC has requested **clarifications before making the final decision,** based on responses to the questions raised, the application can now be cleared by the Chair of the Committee in consultation with the Secretariat and the two principal reviewers of the application.

- Since the Committee recognizes that the mandatory monitoring requirement plays a crucial role in the successful management of the approved GLC programmes/projects, it has been decided to introduce an additional **review of the monitoring reports** by two designated principal reviewers from among the Committee members, before the reports are sent to the Committee at large for final endorsement.

In 2008, GLC followed the review process as outlined in Diagram 2.

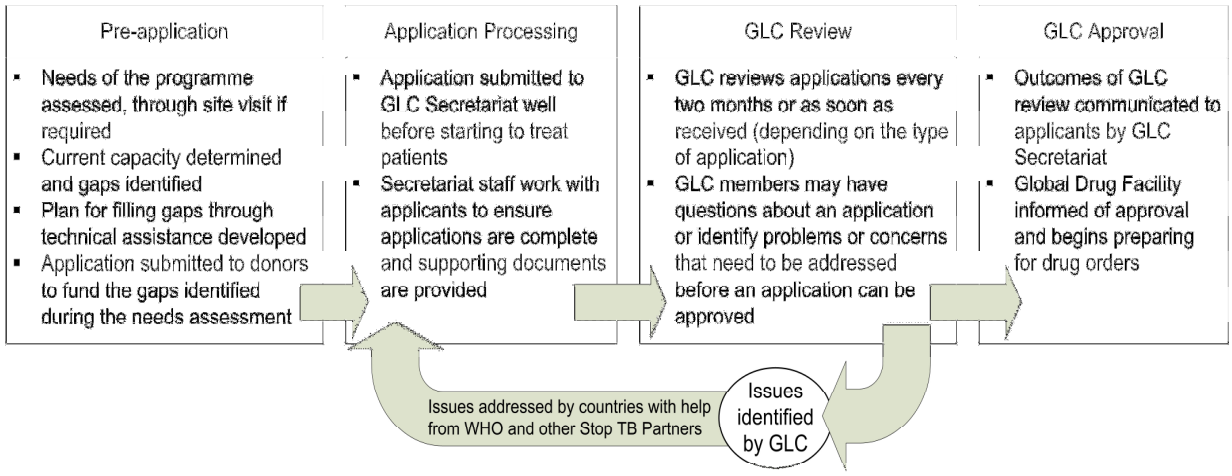


Diagram 2: The GLC Application Process

REVIEW OF APPLICATIONS

In 2008, a total of **43** applications were submitted to the GLC for review, of which **34** were approved by the Committee experts. A further 5 applications were approved following receipt of requests for clarifications made in 2007, bringing the total number of approved applications during 2008 to **39**. The GLC approved 24 new applications, of which 3 were Fast track applications and 15 were expansion applications. Nine applications were awaiting clarifications from the countries on the recommendations made by the GLC and will be reviewed further in 2009.

By December 2008 and since its inception the GLC has granted approval to **60** countries and **93** program sites, which show an increase of 26% in program sites and 39% in the number of patients approved for treatment from 2007. See Annex 1 for the full list of countries and sites.

A total of **19,652** patients were approved for treatment in 2008, which increased the total number of patients approved under GLC initiative since 2000 to **49,858**.

In 2008, the Western Pacific region was approved with the largest number of patients (9113). The European region had the second largest number of patients approved (8297), followed by the African Region (715), the South East Asian Region (600), the Americas (467) and the Eastern Mediterranean (460) regions (Table 1).

Significant progress has been made in the Western Pacific region, where 83% of all patients to be treated under the GLC Initiative were approved in 2008. This increase is explained by the expansion of the programs in China and the Philippines.

REGIONS	2008	TOTAL Since 2000
AFRO	715 (30%)	2395
AMRO	467 (4%)	11166
EMRO	460 (50%)	912
EURO	8297 (39%)	21519
SEARO	600 (21%)	2843
WPRO	9113 (83%)	11023
TOTAL	19652 (39%)	49858

Table 1: GLC approved patients by Region (% of patients approved in 2008)

The European region remains in the lead for the total number of patients approved for treatment together with the Americas and now the Western Pacific Region. The three regions together included **43,708** patients or **83%** of all patients approved under the GLC Initiative .

Programs in the following six countries, China (4,107), Philippines (5,000), and Moldova (4,150), accounted for the majority (67%) of GLC approved patients for programmes/projects approved during 2008.

MONITORING, EVALUATION AND TECHNICAL ASSISTANCE

GLC members consult with a Head of laboratory at a hospital in Latvia that treats MDR-TB patients.

Programs approved by the GLC are monitored annually via site visits to ensure continued adherence to their original protocols and WHO guidelines.

Monitoring and evaluation activities are managed by the GLC Secretariat and WHO regional offices and are carried out by GLC consultants.

In 2008, five program sites received a pre-approval or technical assistance missions on behalf of the GLC (See Table 2).

1	Saratov (Russian Federation)
2	Syria
3	Albania
4	Micronesia
5	Ethiopia

Table 2. Program sites that received a pre-approval mission

Following these technical assistance missions, Ethiopia, Mozambique, Micronesia and Saratov have received GLC approval.

In 2008, 35 sites received a monitoring and evaluation visit from GLC experts (See Table 3). Each visit resulted in a formal report cleared by the Committee with conclusions and recommendations shared with the relevant implementing agency in the country and partners.

In general, missions identified the key bottlenecks of laboratory capacity, drug management and human resources. The mission recommended and provided guidance to overcome the situations as per country context.

1	Arkhangelsk (Russian Federation)
2	Armenia
3	Azerbaijan
4	Belarus
5	Burkina Faso
6	Cambodia
7	China
8	Costa Rica
9	Dominican Republic
10	DRC
11	Ecuador
12	El Salvador
13	Haiti
14	Kaliningrad (Russian Federation)
15	Kenya
16	Khakasiya (Russian Federation)
17	Komi Republic
18	Komi Republic
19	Kyrgystan
20	Kyrgyzstan
21	Lesotho
22	Moldova
23	Mongolia
24	Nicaragua
25	Pakistan
26	Paraguay
27	Peru
28	Philippines
29	Romania
30	Syria
31	Tanzania
32	Tomsk (Russian Federation)
33	Tunisia
34	Uganda
35	Uzbekistan

Table 3. Program sites that received a monitoring mission

PARTNERING WITH OTHER ORGANIZATIONS

Enhancing diagnostic capacity is a critical step in order to scale up any MDR-TB project

In 2008, the GLC Initiative continued collaboration with the *United States Agency for International Development (USAID), The US President's Emergency Plan for AIDS Relief (PEPFAR), The Lilly MDR-TB Partnership, UNITAID and the Global Fund (GF)*.

UNITAID: As it was envisioned in July 2007, the partnership between the GLC Initiative and UNITAID resulted in provision of affordable and quality-assured SLDs for MDR-TB programs in at least 12 low- and middle-income countries, therefore contributing to the scale-up of MDR-TB management worldwide.

Under this partnership scheme, UNITAID initially committed US$20.8 million to procure and supply SLDs (for an estimated 4,716 patient treatments in 17 countries) but in 2008 increased its contribution to US$ 37,7 million. In addition, UNITAID has committed funds in the amount of US$ 11,4 million for establishment of the rotating stockpile of SLD in order to decrease lead times for procurement. UNITAID funding has already benefited 13 program sites and enabled 1,673 patient treatments.

The Global Fund: The GLC Initiative's collaboration with the GF has continued to strengthen and evolve in 2008 based on the Memorandum of Understanding (MOU) signed in November of 2007. To help control the spread of drug resistance and ensure access to affordable, quality-

assured drugs, the GF has mandated GLC Review for all of its programs with an MDR-TB component and procurement of SLDs. Through this partnership, the GF is contributing US$50,000 per grant per year for GLC activities under a cost-sharing scheme. The GF has contributed about US$ 0.65 million or 39% of the planned amount in 2008. The revision of the MOU that was initiated in 2008 is planned to improve the flow of funds and upgrade the reporting on developments in country MDR-TB programmes/projects.

At the end of 2008, there were **67** country programmes/projects with **41,452** patients approved by the GLC that were also approved by the GF for funding. This represented **69%** of all GLC programs and **83%** of all patients. The overall number of country programmes/projects that have benefitted from GLC support has reached 93 .

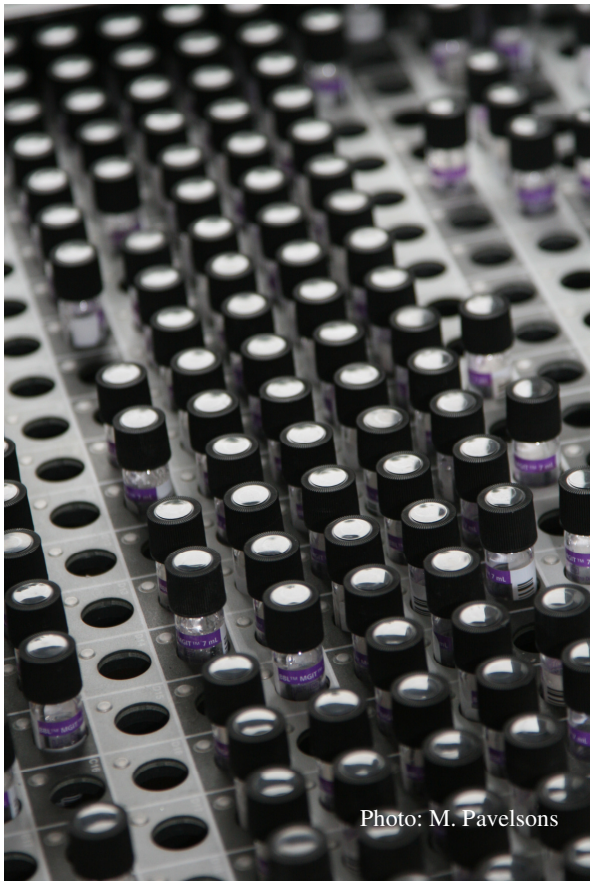


Photo: M. Pavelsons

The US President's Emergency Plan for AIDS Relief (PEPFAR): The scale-up of MDR-TB management called for by the WHO and Stop TB Partnership in the Global Plan and MDR/XDR-TB response plan has started to accelerate as countries begin to receive more financing for implementation, equipment and medical supplies from the GF and UNITAID; thus, in 2008 PEPFAR provided financing to the GLC Initiative to assist countries in absorbing the increased funding from the GF by strengthening their national program capacity for MDR-TB management and further expanding their application of available TB diagnostics, infection control approaches and drug management practices.

The Lilly MDR-TB partnership: The Lilly Partnership provided funds for technical assistance to MDR-TB programme/project implementation in non-GF countries in collaboration with the Eli Lilly partners and the funding for the training course for MDR-TB consultants. In 2008 the Lilly MDR-TB Partnership reiterated its support and supplied sizeable quantities of several key SLDs at concessional prices to the programmes/projects approved by the GLC.

Overall, donor support to the country programmes/projects within the framework of the GLC Initiative has increased in comparison to previous years.

FINDINGS FROM GLC-APPROVED PROGRAMS

Thirty-seven (37) programs from Azerbaijan, Armenia (MSF), Bolivia, Burkina Faso, Cambodia, Costa Rica, Dominican Republic, El Salvador, Estonia, Egypt, Georgia, Guinea, Haiti, Jordan, Honduras, Kyrgyzstan, Latvia, Lebanon, Lesotho, Mexico, Moldova, Mongolia, Nepal, Nicaragua, Russian Federation (Arkhangelsk, Orel, Tomsk),Paraguay, Peru, Philippines, Romania, Syria, Tunisia, Uruguay and Uzbekistan (Tashkent, Nukus), reported their notification and treatment outcome data to the GLC in 2008. The data included in the analysis were received in response to the annual data collection call from the GLC Secretariat and represented cumulative findings from 2000 to 2007, analysed in line with international definitions.

Of the total 12,840 MDR-TB patients reported by the 37 programs, 21.1% were classified as new, 15.5% relapse, 4.2% after default, 26.3% failure, 0.5% extrapulmonary and 32,5% other cases. The considerably high proportion of "other" cases demonstrates that the backlog of chronic cases was prioritized in all countries.

The enrollment of patients has increased over the years but due to lengthy treatment times there is a significant delay in reporting final outcomes. Therefore, a substantial proportion of patients (4,451) were reported as "still on treatment" and data will need to be analysed when these patients complete their treatment.

As of end of 2007, **12,840** patients were reported by these programs as completed or still following treatment in GLC programs (Table 4).

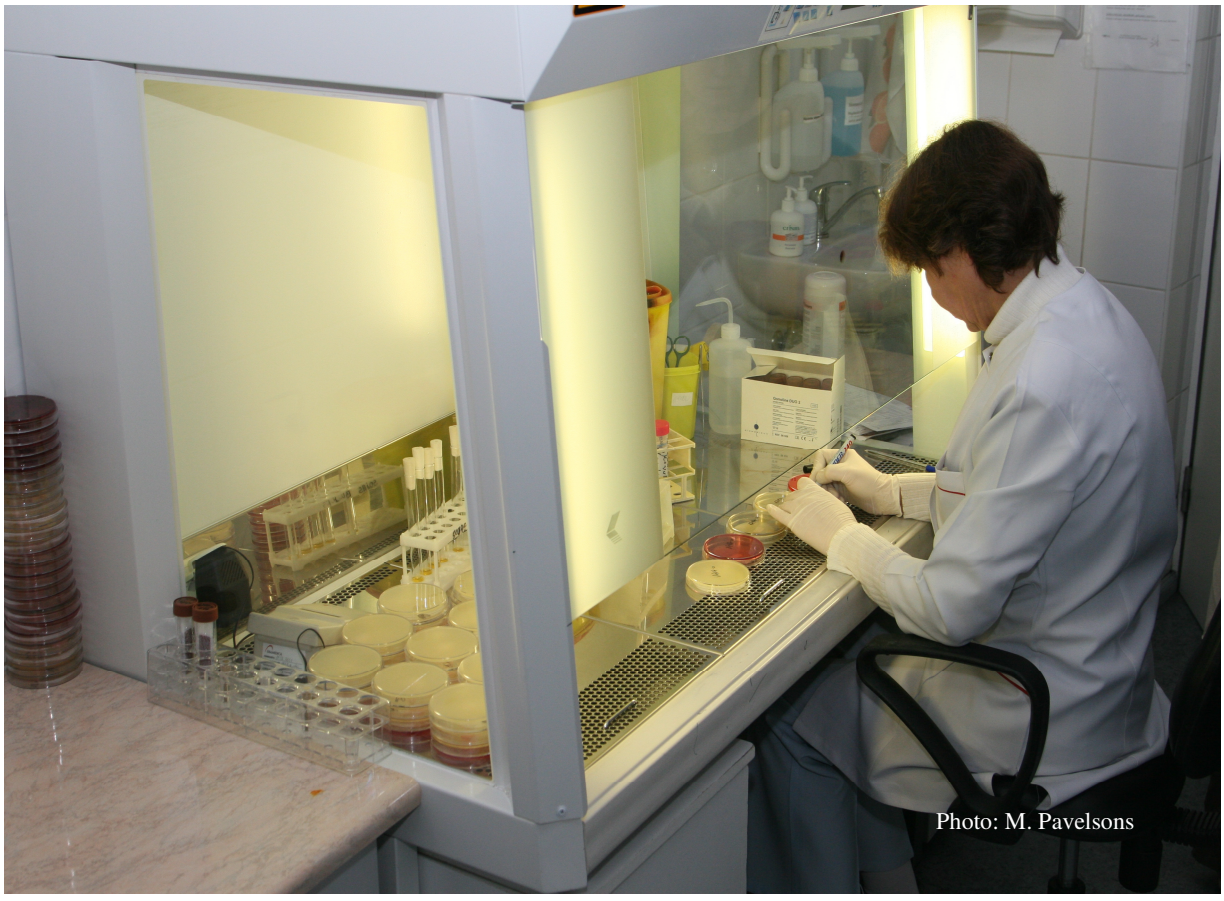
Patients	Patients that completed treatment	Patients that are still on treatment	Grand Total	Total in percentages[3]
New	1606	1097	2703	21.05%
Relapse	1343	641	1984	15.45%
After Default	338	196	534	4.16%
After Failure Cat I	998	679	1677	13.06%
After Failure Cat II	948	757	1705	13.28%
New Extra Pulmonary	55	8	63	0.49%
Other	3101	1073	4174	32.51%
Total	***8389***	***4451***	***12840***	

Table 4: 2007 data on patients having completed and undergoing treatment.

[3] Total does not constitute 100% due to rounding up of the numbers

Of those who completed treatment (8,389), 59% registered treatment success, 13.5% death, 8% failure and 18% default. Although the average treatment success rate was almost 60%, there was a considerable variation between countries.

Treatment success rate may improve in the future as the backlog of chronic cases gets cleared up and coverage of the MDR-TB programs increases. Further operational research and analysis of data from the GLC approved programmes/projects may provide important information for program managers and assist in setting priorities in case management.



Laboratory in TB hospital in Latvia.

PROCUREMENT FOR GLC-APPROVED PROGRAMS

The collaboration between the Green Light Committee and the Global Drug Facility (GDF) for the provision of quality-assured second-line anti-TB medicines to countries in need began in late 2006. Since its inception, this partnership has seen much growth and development.

Drug Procurement in 2008

With the incidence of MDR-TB on the rise, the importance of high quality anti-TB medicines being available to countries in need becomes paramount. GDF saw an increase of 58% in the value of the orders placed for Second-line medicines in 2008 over those purchased in 2007. In 2008, 69 orders were placed by 32 countries through GDF's direct procurement service with a total value of 15.4 million USD (Diagram 3). Additionally, with financial support from UNITAID, 29 orders were placed by 12 countries through GDF's grant service. These orders had a total value of 3.03 million USD. During this reporting period GDF delivered 95 (27 Grant and 68 DP) orders worth a total value of approximately 12 million USD.

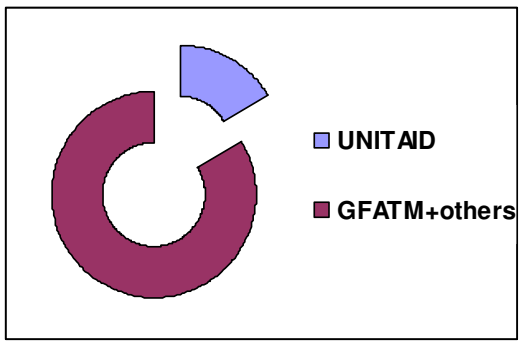


Diagram 3: Financing sources for executed SLD orders in 2008

Some Challenges faced in 2008

Once of the key challenges in the fight against MDR-TB is ensuring the availability of quality-assured SLDs. GDF continues to rely on single sources for most of the SLDs that it provides to countries.

As a result, in 2008, GDF encountered some difficulties with the continuous availability of a number of its products. These included:

(i) Amikacin 500mg powder for injection: For this product, GDF experienced irregular deliveries from Medochemie (the manufacturer) in terms of quantities committed through firm orders, which affected delivery lead times negatively. However, GDF and the IDA Foundation managed to secure a second supplier for this product (Mylan) in the fourth quarter of 2008.

(ii) PAS acid: This single source product from Jacobus also faced supply interruptions, which negatively impacted GDF's ability to meet the delivery targets requested by programmes/projects. The availability issue of PAS acid is related both to the production capacity of the manufacturer versus the high demand, but also to the fact that the manufacturer closed its plant for 6 weeks at a time in order to increase its production capacity during the first and fourth quarters of 2008. GDF continues to explore solutions to this problem with IDA and the manufacturer in early 2009. In the interim,

GDF identified and assessed the quality of an alternative source - PAS sodium - which was approved to cover delivery gaps from the primary supplier.

(iii) Capreomycin: In 2008 GDF flagged the risk of a potential shortfall in the supply of capreomycin from Eli Lilly which is currently the only supplier offering capreomycin that meets GDF Quality Assurance standards. As a result of pro-active communication with the manufacturer, the risk was averted. Eli Lilly agreed to increase its annual production of capreomycin from 360,000 vials to 860,000. In view of the demand increase for 2008 and of the forecasted needs presented for 2009, the company agreed furthermore to produce an additional 560,000 vials in 2009 for a total quota of 1,400,000 million vials in that year. However the anticipated 2009 drug needs are estimated at 2,000,000 vials, therefore GDF will continue to explore avenues to fill this gap in supply.

(iv) Clofazimine: In 2008, GDF was able to procure small quantities of clofazimine through the Leprosy Program at WHO that procures the medicine through Novartis. However, as the demand from the programs for this drug increased, this supply channel could not support the volumes needed for MDR-TB programmes/projects. GDF together with the GLC partners therefore opened a communication channel with Novartis to attempt to secure clofazimine through this company. However, as clofazimine is not currently recognized as a medicine for the treatment of TB, Novartis refused to provide the medicine to GDF/GLC for the treatment of MDR-TB patients.

(v) Moxifloxacin: Another area of difficulty encountered in 2008 was with the procurement of moxifloxacin from Bayer. GDF and GLC attempted, through negotiation, to secure additional supplies of this expensive product at concessional prices from Bayer. However, Bayer was reluctant to provide moxifloxacin as there are currently no long-term studies proving the safety of moxifloxacin in the treatment of MDR-TB. In fact, in 2008 Bayer ceased to supply even the limited volumes of moxifloxacin to GDF through its intermediary, IDA. As an interim solution GDF was able to secure the procurement of moxifloxacin through a wholesaler used by IDA.

Additional Prequalified Medicines

During the reporting period, four (4) new dossiers for second-line anti-TB drugs were submitted and accepted for evaluation by the WHO Prequalification Programme (PQ). Drugs covered by the dossiers included: capreomycin, cycloserine, levofloxacin and prothionamide. GDF will continue to monitor the status of these submissions and communicate with suppliers to ensure that all necessary requested actions are taken to ensure timely approval by WHO PQ. GDF relies primarily on the positive outcomes of the WHO PQ assessment process to initiate the procurement and supply of second-line anti-TB medicines.

Strengthening relationships within the Procurement and Supply Chain

GDF continues to engage the services of the International Dispensary Association (IDA) as its procurement agent for second-line drugs as per the ongoing contract, valid until July 2010. 2008 saw the further growth of this relationship as IDA and GDF combined their services to use one specifically designed procurement software, the Order Management System (OMS), specifically networked to increase the efficiency of the procurement process and communication at all steps in the procurement chain. Through the OMS, the programmes/projects are informed about each step in the supply process, including order placement, receipt of payment, expected delivery dates, as well as the relevant shipping details and necessary documentation.

Manufacturers

In May 2008, GDF held it's biannual stakeholders meeting in Mumbai, India. This meeting was the first stakeholders meeting to include second-line manufacturers. The focus of the meeting was to identify and problem solve for identified bottlenecks within the procurement and supply chain. GDF also used this opportunity to open communication channels with potential suppliers with presentations regarding GDF, the WHO PQ Programme and UNITAID.

Drug Management Sub-Committee (DMSC)

Since its inception in September 2007, the DMSC, convened and hosted by GDF, has been instrumental in assisting GDF to address the growing needs relating to MDR-TB medicines management. The DMSC has assisted GDF in securing interim suppliers to avoid stock out situations, performing market research and identifying potential new sources of second-line anti-TB medicines. Below are a few key areas where the DMSC has aided GDF during this reporting period:

- Identifying producers for levofloxacin, moxifloxacin and kanamycin

- Supporting GDF in negotiations with Eli Lilly regarding capreomycin quota
- Requesting access to particular drugs from suppliers at concessional prices
- Advising GDF on the content of the Strategic Rotating Stockpile, which drugs and percentage of drugs within the drug categories.
- Endorsing provisional approval of some drugs to meet specific country demand due to shortages of supply from the approved source (e.g. capreomycin from Macleods for Russian GLC approved programmes/projects)
- Participating at key meetings convened by GDF to address second-line drug procurement issues

Expression of Interest for Manufacturers

In September 2008, GDF launched a global invitation to manufacturers to submit Expressions of Interest (EOI) to supply second-line anti-TB medicines through GDF. The list of eligible products included: amikacin, amoxicillin + clavunavic acid, capreomycin, clofazamine, cycloserine, ethionamide, kanamycin, levofloxacin, linezolid, moxifloxacin, ofloxacin, prothionamide, PAS acid, PAS sodium, terizidone and thioacetazone.

In total 53 dossiers were received and will be evaluated in Q1 2009 for acceptability by a GDF-appointed Technical Evaluation Committee (TEC) comprising a pharmacist from GDF and key Stop TB Partners in collaboration with experts from WHO PQ. Those product dossiers that are deemed complete by the TEC and in full compliance with the Quality Assurance standards of the EOI will be automatically eligible for submission into the GDF/IDA Tender (scheduled for end Q2 2009).

Support to GLC Programmes/projects by GDF

Several tools were developed and updated with the aim of assisting GLC-approved programmes/projects and programmes with their calculation of drug needs and with the procurement process in general. For this, the SLD estimation tool was updated and re-launched and is available online through the GLC website. An updated Procurement Manual that details the process and guides programs in their procurement is also available online through the GLC and GDF websites.

In 2008, GDF organized, assisted with or participated in many support interventions for programs accessing second-line anti-TB medicines through the GLC Initiative including:

- Presenting on the MDR-TB Procurement Process of the GLC mechanism in the Workshop on MDR-TB Control Management in the CIS setting, organized by Partners in Health and held in Istanbul, Turkey.
- Presenting the GDF process for the Quality Assurance of TB Medicines at "Streamlining TB case, medicine and commodity management information: strengthening health

systems response" organized by Management Science for Health (MSH) in Paris, France.

- Presenting on Drug Management of second-line anti-TB medicines at a conference on "Post-graduate course clinical and programmatic management of MDR-TB and XDR-TB" organized by the IUATLD in Paris, France.
- Presenting an overview of the technical assistance available for drug management in GLC programmes/projects at the GLC consultants workshop in Paris, France.
- Presenting on quality assurance of drug-resistant anti-TB medicines and drug management of second-line drugs at the third DR-TB consultants' course organized by GLC in Lima, Peru.
- Together with GLC, providing the drug management component to Monitoring and Evaluation missions of GLC Programs in 2008 at sites including Burkina Faso, Democratic Republic of the Congo, Haiti, Mongolia, Nepal, Peru and the Philippines.

As global awareness and support for the battle against MDR-TB swell, GDF anticipates a marked increase in second-line anti-TB medicines supply activities. Together with the GLC, GDF will rise to meet this increase in demand and ensure that GLC-approved countries in need continue to receive the high quality anti-TB medicines required to eliminate the threat of drug resistance.

Business Advisory Committee

As GDF has takes on further challenges, with the supply of diagnostic kits, paediatric formulations, second-line anti-TB medicines and increased involvement in country capacity-building, technical assistance and drug management, unique strategic and operational issues can arise.

To execute such a wide range of operations, GDF requires significant expertise and relationships in the fields of raw material manufacturing, pharmacy, product formulation for drugs and diagnostics, quality assurance, regulatory law, contract law, business development, competitive procurement processes, pricing and distribution, strategic planning, technical assistance and capacity building.

In order to ensure this required expertise, the Business Advisory Committee was established by the Stop TB Partnership Coordinating Board in 2006 to assist GDF in identifying and resolving any potential difficulties and opportunities in the areas of procurement operations, strategy implementation, quality systems and resource management, drug management, technical assistance, capacity building, and risk management.

The Committee is composed of approximately 10 members with a strong background in pharmaceutical and diagnostic business operations. Due consideration is given to appropriate Geographic representation and expertise.

In 2008 the BAC held its 3rd and 4th meetings which saw the establishment of three separate subgroups to focus on: 1) Business Operations, 2) Marketing and Procurement and 3) Country Support. Each subgroup works to address issues raised in its particular area.

In 2008 some of the key areas identified and recommendations made were as follows:

- Identifying potential benefits of aligning the GDF Quality Policy with the Global Fund's Quality Policy to ensure a more streamlined approach to drug procurement.

- Identifying additional sources of funding to pursue for technical assistance.

- Providing recommendations on how GDF can better support country financial sustainability.

- Providing assistance with identified bottlenecks in the drug supply chain, including freight complications and prequalification of anti-TB medicines.

- Suggesting a potential compensation system for suppliers holding buffer stocks for GDF.

HUMAN AND FINANCIAL RESOURCES OF THE GLC

In 2008, the **operating budget** for the GLC Initiative comprised **US$ 2,552,535**. It included the cost of managing the day-to-day activities of the GLC, such as reviewing of applications, as well as the human resource costs required to operate the GLC Secretariat and the second-line drug procurement team of the GDF (Diagram 4).

Most of the funds were provided by the long-standing partners of the GLC Initiative (Diagram 3). PEPFAR is the largest contributor, providing 59 % of the total budget for the Initiative. The Global Fund also continued their generous support by providing 25% of the required resources. UNITAID covered 15% of the GLC Initiative operating budget, while WHO provided the remaining 1% of the total funds in 2008.

The operating budget supports the **SLD procurement** function of the GLC Initiative. The procurement budget consists of UNITAID grant to GDF as well as the direct procurement services to countries financed mostly by the Global Fund.

Comparing the expenditure part of the GLC Initiative operating budget to the expenditure part of the SLD procurement budget that is handled through the GLC Initiative, 92 % were spent on SLDs for the GLC-approved programmes/projects (77% through the Global Fund and 15% with UNITAID funding), 4 % were spent on human resources, 3% on technical assistance to countries to prepare and submit applications to the GLC and monitoring of the on-going programmes/projects and the remaining 1 % was spent on the GLC review process (Diagram 5 and Table 6).

Partner/Donor	**Contribution** (in US $)
PEPFAR	1,500,000
TGF	650,000
UNITAID	375,471
WHO	27,064
Total	**2,552,535**

Table 5: 2008 Income for operational budget

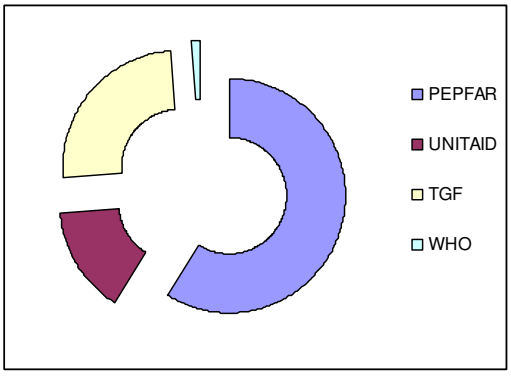


Diagram 4: Operating budget

Type of expenditure	**Expenditure in US$**
Drugs GFATM	15,400,000
Drugs UNITAID	3,030,000
M&E and TA	702,356
Review process	250,397
HR Secretariat	746,535
Total	**20,129,288**

Table 6: 2008 Expenditure for operations and drugs

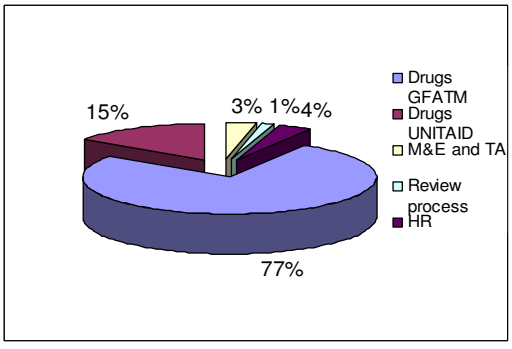


Diagram 5: GLC Initiative expenditure

In addition to the funds used to support the management of the day-to-day activities of the GLC Initiative, in 2008 the Initiative regulated and monitored the overall implementation of country programmes/projects on management of DR-TB, that received major contributions from such funding organizations like The Global Fund. The GLC Initiative therefore demonstrates an effective added value in the services that it delivers to country programmes/projects.

Additional funding for patient treatments

As the need for quality-assured second-line anti-TB medicines grows, GDF and one of its key partners, UNITAID, continue to strive to meet this demand. In 2008 UNITAID demonstrated its commitment to the fight against MDR-TB by increasing its contribution to MDR-TB treatment scale-up by an additional US $16,840,000 (from US $20,820,000 to US $37,662,000) allowing for a revised total of 5,756 MDR-TB patients (previously 4,716 patients) to benefit from the treatments provided through GDF (2007 - 2011).

Complementary to the MDR-TB scale-up initiative, the UNITAID board approved, in April 2008, to augment the existing stockpile of second-line drugs for 800 patient treatments by medicines for an additional 5,000 patient treatments. This Strategic Rotating Stockpile (SRS) enhancement will provide improved, accelerated services for a major portion of newly enrolled patients under GLC-approved country projects and programmes. Through this initiative, suppliers will be able to plan more effectively, including better production and capital investment planning, both in the medium- and long-term, as orders will be subject to less volatility and uncertainty.

Prospects for the year 2009

As the number of countries applying to the GLC rapidly increases, so will the needs of the GLC Initiative. Countries with approved applications from 2008 are expected to scale up implementation of their programs in 2009, thereby increasing the number of patients being treated under the GLC Initiative.

While the additional funding that is expected from UNITAID and The Global Fund would allow more resources to be allocated towards the provision of affordable and quality-assured SLDs, the GLC will also need to substantially increase the total amount of technical support provided to the countries in order to strengthen the regional and country capacity to meet the upcoming demand.

The GLC will continue to explore new partnership opportunities to raise more funds and expand its working collaboration with the existing as well as new partners to further the achievement of global targets in MDR-TB control.

Human Resources

In 2008, GDF continued to secure additional funding for supplies and the provision of quality-approved second-line anti-TB medicines as well as increasing its operational support. In 2008, GDF secured a full-time pharmacist/technical officer to advise on quality assurance

issues pertaining to first and second line medicines (a position formally filled by a secondment from Médecins Sans Frontières).

Additionally, in 2008, a procurement officer was engaged dedicated to the UNITAID portfolio of projects, including MDR-TB Scale Up countries, and facilitating the implementation of the programs in these countries.

The GLC Secretariat team was strengthened near the end of 2008 by the addition of two medical officers who are working closely with the GLC-approved programmes/projects and the WHO country and regional offices to provide technical assistance as well as to coordinate and facilitate the monitoring of the GLC-approved programmes/ projects.

ANNEX 1. List of GLC approved programs

GLC approved cohorts by Year

Year	No. of applications approved	PatientCohort	Cumulative Cohort
2000	2 Applications	1000 Patients	1000
2001	3 Applications	1180 Patients	2180
2002	1 Applications	800 Patients	2980
2003	9 Applications	2099 Patients	5079
2004	17 Applications	4630 Patients	9709
2005	13 Applications	2291 Patients	12000
2006	25 Applications	12954 Patients	24954
2007	25 Applications	5252 Patients	30206
2008	39 Applications	19652 Patients	49858
Total approved applications	134	Total Approved Patient Cohorts	49858

GLC Program Applications

As at 31 December 2008

Total Approved applications - 134

Total Approved Countries - 60

Total Approved programs - 93

TOTAL APPROVED PATIENTS: 49858

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
AFRO									
	Burkina Faso	Burkina Faso	2005	13.03.2006	New	approved	10	NTP	Yes
			2007	22.05.2007	Expansion	approved	40	GF & UNITAID	N/A
				Total approved patients in Country:			50		
	Cameroon	Cameroon	2008	10.09.2008	New	approved	20	NTP	Yes
				Total approved patients in Country:			20		
	Democratic Republic of the	DRC	2006	19.06.2006	New	approved	1100	GF & UNITAID	Yes
				Total approved patients in Country:			1100		
	Ethiopia	Ethiopia	2008	20.08.2008	New	approved	45	GF	Yes
				Total approved patients in Country:			45		
	Guinea	Guinea	2006	19.06.2006	New	approved	30	UNITAID-Mission	Yes
				Total approved patients in Country:			30		
	Kenya	Kenya	2004	01.12.2004	New	approved	50	GF & UNITAID	Yes
				Total approved patients in Country:			50		
	Lesotho	Lesotho	2006	15.01.2007	New Fast Track	approved	40	PIH	Yes
			2007	17.09.2007	Expansion	approved	60	PIH & UNITAID	N/A
			2008	23.05.2008	Expansion	approved	200	PIH & UNITAID	N/A
				Total approved patients in Country:			300		
	Mozambique	Mozambique	2007	24.10.2008	New	approved	400	GF & UNITAID	Yes
				Total approved patients in Country:			400		
	Rwanda	Rwanda	2006	04.08.2006	New	approved	300	GF	Yes
				Total approved patients in Country:			300		
	Uganda	Uganda	2006	02.03.2007	New	approved	50	GF-Wellcome	No
				Total approved patients in Country:			50		
	United Republic of Tanzania	Tanzania	2008	28.02.2008	New	approved	50	GF	Yes
				Total approved patients in Country:			50		
				Total approved patients in Region:			**2395**		

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
AMRO									
	Belize	Belize	2006	24.07.2006	New	approved	1	NTP	No
				Total approved patients in Country:			1		
	Bolivia	Bolivia	2003	25.07.2003	New	approved	10	GF	Yes
			2005	15.11.2005	Expansion	approved	100	GF	N/A
			2008	10.09.2008	Expansion	approved	50	GF	N/A
				Total approved patients in Country:			160		
	Costa Rica	Costa Rica	2002	25.06.2003	New	approved	14	NTP	Yes
			2005	15.11.2005	Expansion	approved	10	NTP	N/A
				Total approved patients in Country:			24		
	Dominican Republic	Dominican Republic	2004	11.04.2005	New	approved	125	GF	Yes
			2007	17.09.2007	Expansion	approved	300	GF & UNITAID	N/A
				Total approved patients in Country:			425		
	Ecuador	Ecuador	2005	19.06.2006	New	approved	120	GF	Yes
				Total approved patients in Country:			120		
	El Salvador	El Salvador	2004	26.04.2004	New	approved	57	GF	Yes
				Total approved patients in Country:			57		
	Guatemala	Guatemala	2007	05.09.2007	New	approved	60	GF	Yes
				Total approved patients in Country:			60		
	Haiti	Haiti/PIH-NTP	2003	28.08.2003	New	approved	60	PIH	Yes
			2007	14.08.2008	Expansion	approved	150	PIH & UNITAID	N/A
		Haiti-GHESKIO	2007	27.07.2007	New Fast Track	approved	24	PIH	Yes
				Total approved patients in Country:			234		
	Honduras	Honduras	2003	26.02.2004	New	approved	50	GF	Yes
				Total approved patients in Country:			50		
	Mexico	Mexico	2002	12.02.2003	New	Finalized	125	NTP	Yes
			2008	29.10.2008	Expansion	approved	242	NTP	N/A
		Mexico Puentes	2008	29.10.2008	New Fast Track	approved	25	USAID	No
				Total approved patients in Country:			392		
	Nicaragua	Nicaragua	2004	10.07.2004	New	approved	21	GF	Yes
				Total approved patients in Country:			21		
	Paraguay	Paraguay	2005	21.08.2006	New	approved	20	GF	Yes
				Total approved patients in Country:			20		

AMRO (*continued*)

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
	Peru	Peru NTP	2003	17.11.2003	new	approved	500	GF	No
			2004	01.06.2004	Expansion	approved	750	GF	No
			2004	25.09.2004	Expansion	approved	750	GF	No
			2006	13.03.2006	Expansion	approved	6000	GF	No
		Peru PIH	2000	23.10.2000	New	approved	800	PIH	Yes
			2002	12.06.2002	Expansion	approved	800	PIH	N/A
				Total approved patients in Country:			9600		
	Uruguay	Uruguay	2007	26.06.2007	New Fast Track	approved	2	NTP	Yes
				Total approved patients in Country:			2		
				Total approved patients in Region:			**11166**		
EMRO									
	Egypt	Egypt	2003	10.01.2005	New	approved	75	GF	Yes
			2007	05.09.2007	Expansion	approved	86	GF	N/A
				Total approved patients in Country:			161		
	Jordan	Jordan	2003	23.11.2004	New	approved	45	GF	Yes
			2008	05.02.2008	Expansion	approved	60	GF	N/A
				Total approved patients in Country:			105		
	Lebanon	Lebanon	2003	16.03.2004	New	approved	20	NTP	Yes
				Total approved patients in Country:			20		
	Pakistan	Karachi	2008	13.11.2008	New	approved	400	GF	Yes
				Total approved patients in Country:			400		
	Syrian Arab Republic	Syria	2003	05.11.2004	New	approved	161	NTP-GF	Yes
				Total approved patients in Country:			161		
	Tunisia	Tunisia	2003	09.03.2005	New	approved	65	NTP	Yes
				Total approved patients in Country:			65		
				Total approved patients in Region:			**912**		

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
EURO									
	Armenia	Armenia/GF	2007	22.04.2008	New	approved	180	GF	Yes
		Armenia/MSF	2006	24.07.2006	New	approved	90	MSF-F	Yes
				Total approved patients in Country:			270		
	Azerbaijan	Azerbaijan	2004	05.08.2005	New	approved	100	GF	Yes
			2007	17.09.2007	Expansion	approved	100	GF & UNITAID	N/A
			2007	15.11.2007	Expansion	approved	20	GF & UNITAID	N/A
				Total approved patients in Country:			220		
	Belarus	Belarus	2008	22.04.2008	New	approved	200	GF	Yes
				Total approved patients in Country:			200		
	Bulgaria	Bulgaria	2008	13.11.2008	New	approved	50	GF	Yes
				Total approved patients in Country:			50		
	Estonia	Estonia	2000	30.03.2001	New	approved	200	NTP	Yes
			2004	23.06.2004	Expansion	approved	200	NTP	N/A
			2008	22.04.2008	Expansion	approved	300	NTP	N/A
				Total approved patients in Country:			700		
	Georgia	Abkhazia	2004	05.11.2004	New	approved	30	MSF-F	Yes
			2005	14.11.2005	Expansion	approved	126	MSF-F	N/A
		Georgia/GF	2006	31.08.2006	New	approved	800	GF	Yes
				Total approved patients in Country:			956		
	Kazakhstan	Kazakhstan	2006	15.01.2007	New	approved	380	GF	Yes
				Total approved patients in Country:			380		
	Kyrgyzstan	Kyrgyzstan	2004	27.10.2004	New	approved	50	GF	Yes
			2006	06.09.2006	Expansion	approved	50	GF	N/A
			2007	02.07.2007	Expansion	approved	1780	GF & UNITAID	Yes
				Total approved patients in Country:			1880		
	Latvia	Latvia	2000	13.02.2001	New	approved	350	NTP	Yes
				Total approved patients in Country:			350		
	Lithuania	Lithuania	2005	15.11.2005	New	approved	972	NTP-USAID	Yes
				Total approved patients in Country:			972		
	Moldova	Moldova	2004	28.02.2005	New	approved	100	GF	Yes
			2006	11.11.2006	Expansion	approved	600	GF & UNITAID	N/A
			2008	22.04.2008	Expansion	approved	4150	GF & UNITAID	N/A
				Total approved patients in Country:			4850		
	Republic of Serbia	Serbia	2008	21.11.2008	New	approved	100	GF	Yes
				Total approved patients in Country:			100		

EURO (*continued*)

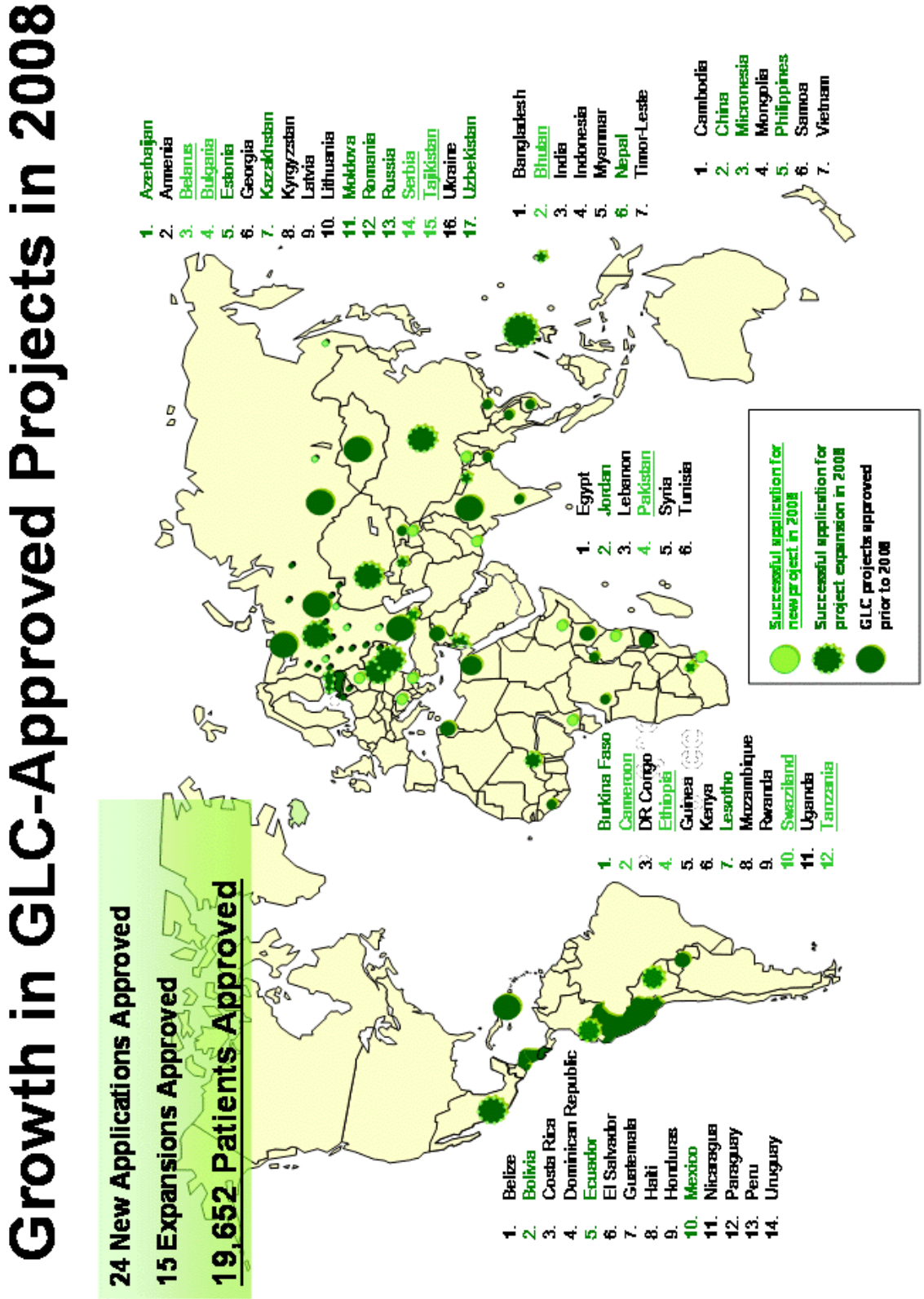
WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
	Romania	Romania	2004	26.11.2004	New	approved	200	GF	Yes
			2005	15.11.2005	Expansion	approved	200	GF	N/A
			2008	24.10.2008	Expansion	approved	320	GF	N/A
					Total approved patients in Country:		720		
	Russian Federation	Adygeya	2008	18.09.2008	New Fast Track	approved	50	GF	RHCF
		Altai Krai	2007	09.04.2008	New	approved	450	GF	RHCF
		Arkhangelsk	2003	02.05.2003	New	approved	890	GF	Yes
		Belgorod	2006	11.11.2006	New	approved	250	GF	RHCF
		Buryatiya	2008	28.04.2008	New	approved	245	GF	RHCF
		Chuvashiya	2006	11.11.2006	New	approved	70	GF	RHCF
		CTRI	2007	08.02.2008	New	approved	80	GF	RHCF
		Ingushetia	2007	08.02.2008	New	approved	50	GF	RHCF
		Ivanovo	2003	03.10.2003	New	approved	200	GF	RHCF
		Kaliningrad	2007	18.01.2008	New	approved	50	GF	RHCF
		Karelia	2006	27.04.2007	New	approved	300	GF	RHCF
		Khakasiya	2005	19.06.2006	New	approved	324	GF	RHCF
		Komi Republic	2007	08.02.2008	New	approved	280	GF	RHCF
		Mariy-El	2006	11.11.2006	New	approved	204	GF	RHCF
		Novgorod	2006	15.01.2007	New	approved	240	GF	RHCF
		Novosibirsk	2006	11.11.2006	New	approved	300	GF	RHCF
		Orel	2001	01.04.2003	New	approved	200	CDC	Yes
			2006	06.07.2006	Expansion	approved	200	CDC & WHO	RHCF
		Pskov	2007	08.02.2008	New	approved	250	GF	RHCF
		RIPP MMA	2008	05.03.2008	New	approved	75	GF	RHCF
		Russia/Tomsk	2001	13.09.2001	New	approved	630	PIH	Yes
			2004	19.11.2004	New	approved	300	GF	N/A
			2005	26.10.2005	Expansion	approved	300	GF	N/A
			2006	01.12.2006	Expansion	approved	350	GF	N/A
		Samara	2006	11.11.2006	New	approved	760	GF	RHCF
		Saratov	2008	09.10.2008	New	approved	360	GF	RHCF
		St Petersburg RIPP	2008	25.06.2008	New	approved	50	GF	RHCF
		Tumen	2007	09.05.2008	New	approved	192	GF	RHCF
		Ural	2007	25.06.2008	New	approved	45	GF	RHCF
		Vladimir	2005	19.06.2006	New	approved	210	GF	RHCF
					Total approved patients in Country:		7905		

EURO (*continued*)

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
	Ukraine	Ukraine	2006	27.04.2007	New	withdrawn by GLC	40	Foundation for dev. of	Yes
				Total approved patients in Country:			40		
	Uzbekistan	UZB/MSF	2002	21.02.2003	New	approved	100	MSF-H	Yes
			2004	18.11.2004	Expansion	approved	846	MSF-H	N/A
			2008	22.04.2008	Expansion	approved	700	MSF-H	N/A
		UZB/NTP	2006	25.08.2006	New	approved	60	GF	Yes
			2008	08.07.2008	Expansion	approved	120	GF & UNITAID	N/A
		UZB/Prison	2007	05.09.2007	New	approved	100	GF & UNITAID	Yes
				Total approved patients in Country:			1926		
				Total approved patients in Region:			**21519**		
SEARO									
	Bangladesh	Bangladesh	2006	19.06.2006	New	approved	700	GF	Yes
				Total approved patients in Country:			700		
	India	IND/LRS	2002	06.04.2005	New	withdrawn by GLC	100	LRS	Yes
		India/NTP	2006	13.03.2007	New	approved	100	GF	Yes
				Total approved patients in Country:			200		
	Indonesia	Indonesia	2007	21.11.2007	New	approved	100	GF	Yes
				Total approved patients in Country:			100		
	Myanmar	Myanmar	2007	21.11.2007	New	approved	275	UNITAID & NTP	Yes
				Total approved patients in Country:			275		
	Nepal	Nepal	2003	26.02.2004	New	approved	350	GF	Yes
			2007	02.03.2007	Expansion	approved	600	GF & UNITAID	N/A
			2008	09.10.2008	Expansion	approved	600	GF	N/A
				Total approved patients in Country:			1550		
	Timor-Leste	Timor-Leste	2005	14.11.2005	New	approved	18	UNITAID & NTP	Yes
				Total approved patients in Country:			18		
				Total approved patients in Region:			**2843**		

WHO/ RO	Country	Program	Year Applied	Date Approved	Type	Status	Size Cohort	Funds	Signed LOA
WPRO									
	Cambodia	Cambodia	2006	19.06.2006	New	approved	30	CAMELIA & CHC	Yes
			2007	14.08.2007	Expansion	approved	100	CHC & UNITAID	N/A
				Total approved patients in Country:			130		
	China	China	2006	14.03.2007	New	approved	354	GF	Yes
			2008	18.09.2008	Expansion	approved	3360	GF	N/A
			2008	12.11.2008	Expansion	approved	747	GF	N/A
				Total approved patients in Country:			4461		
	Micronesia (Federated States of	Micronesia	2007	18.01.2008	New Fast Track	approved	1	GF	Yes
			2008	04.07.2008	Expansion	approved	5	GF	N/A
				Total approved patients in Country:			6		
	Mongolia	Mongolia	2005	18.01.2006	New	approved	375	GF	Yes
				Total approved patients in Country:			375		
	Philippines	Philippines TDF	2000	05.10.2000	New	approved	200	NTP	Yes
			2003	30.03.2004	Expansion	approved	750	GF	N/A
			2008	07.05.2008	Expansion	approved	5000	GF	N/A
				Total approved patients in Country:			5950		
	Samoa	Samoa	2007	19.07.2007	New Fast Track	approved	1	MoH	Yes
				Total approved patients in Country:			1		
	Viet Nam	Viet Nam	2007	29.06.2007	New	approved	100	GF	Yes
				Total approved patients in Country:			100		
				Total approved patients in Region:			**11023**		

ANNEX 2.


Growth in GLC-Approved Projects in 2008
24 New Applications Approved
15 Expansions Approved
19,652 Patients Approved
1. Azerbaijan
2. Armenia
3. Belarus
4. Bulgaria
5. Estonia
6. Georgia
7. Kazakhstan
8. Kyrgyzstan
9. Latvia
10. Lithuania
11. Moldova
12. Romania
13. Russia
14. Serbia
15. Tajikistan
16. Ukraine
17. Uzbekistan
1. Bangladesh
2. Bhutan
3. India
4. Indonesia
5. Myanmar
6. Nepal
7. Timor-Leste
1. Cambodia
2. China
3. Micronesia
4. Mongolia
5. Philippines
6. Samoa
7. Vietnam
1. Egypt
2. Jordan
3. Lebanon
4. Pakistan
5. Syria
6. Tunisia
1. Burkina Faso
2. Cameroon
3. DR Congo
4. Ethiopia
5. Guinea
6. Kenya
7. Lesotho
8. Mozambique
9. Rwanda
10. Swaziland
11. Uganda
12. Tanzania
1. Belize
2. Bolivia
3. Costa Rica
4. Dominican Republic
5. Ecuador
6. El Salvador
7. Guatemala
8. Haiti
9. Honduras
10. Mexico
11. Nicaragua
12. Paraguay
13. Peru
14. Uruguay
Successful application for new project in 2008
Successful application for project expansion in 2008
GLC projects approved prior to 2008

ANNEX 3. Procurement of SLDs in 2008

GDF core functions	Activity	Results		
		Current reporting period (2008)	Previous year (2007)	Cumulative (2001-2008)
Countries receiving deliveries	No. of countries that received second-line deliveries	37	34	42
GDF core functions	**Activity**	**Current reporting period (2008)**	**Previous year (2007)**	**Cumulative (2007 -**
Second-line Grants approved	Value of GDF second-line grants approved, in US$ '000	12,875[4]	14,265	27,140
	No. of patient treatments approved for grants	1,040	4,716	5,756
Anti-TB Drug Prequalification & GMP Compliance[5]	No. of second-line manufacturers that are WHO GMP[6] compliant (out of 8 manufacturers used by GDF)	8	8	8
	No. of second-line prequalified products from those listed in the GDF catalogue (out of 14)	2 of 14	2 of 10	2
	No. of second-line prequalified products from those listed in the GDF catalogue (out of 14) that have 2 of more suppliers	1	0	1
Area	**Indicator**	**GDF price per tablet/vial**	**Lowest Other Price per tablet/vial**	
Direct Procurement (Affordability)	GDF drug price (US$) compared to the lowest price offered by a competitive selection of international suppliers[7]			
	Capreomycin	3.2100	13.70	
	Cycloserine	.5102	.6900	
	Kanamycin (powder)	.5805	.5300	
	Ofloxacin	.0360	n/a	
Service	**Indicator**	**Results**		
		Current reporting period (2008)	**Previous year (2007)**	**Cumulative (2007-onwards)**
Second-line Direct Procurement	Number of orders placed	69	62	131
	Number of Countries placing orders	32	30	n/a
	Total value of orders placed (product costs only, US$)	$15,441,769	$9,750,306	$25,192,075
	Number of requests delivered	68	54	122
	Number of requests delivered (Global Fund orders)	*44*	*30*	*74*
	Countries receiving deliveries (all orders)	30	30	

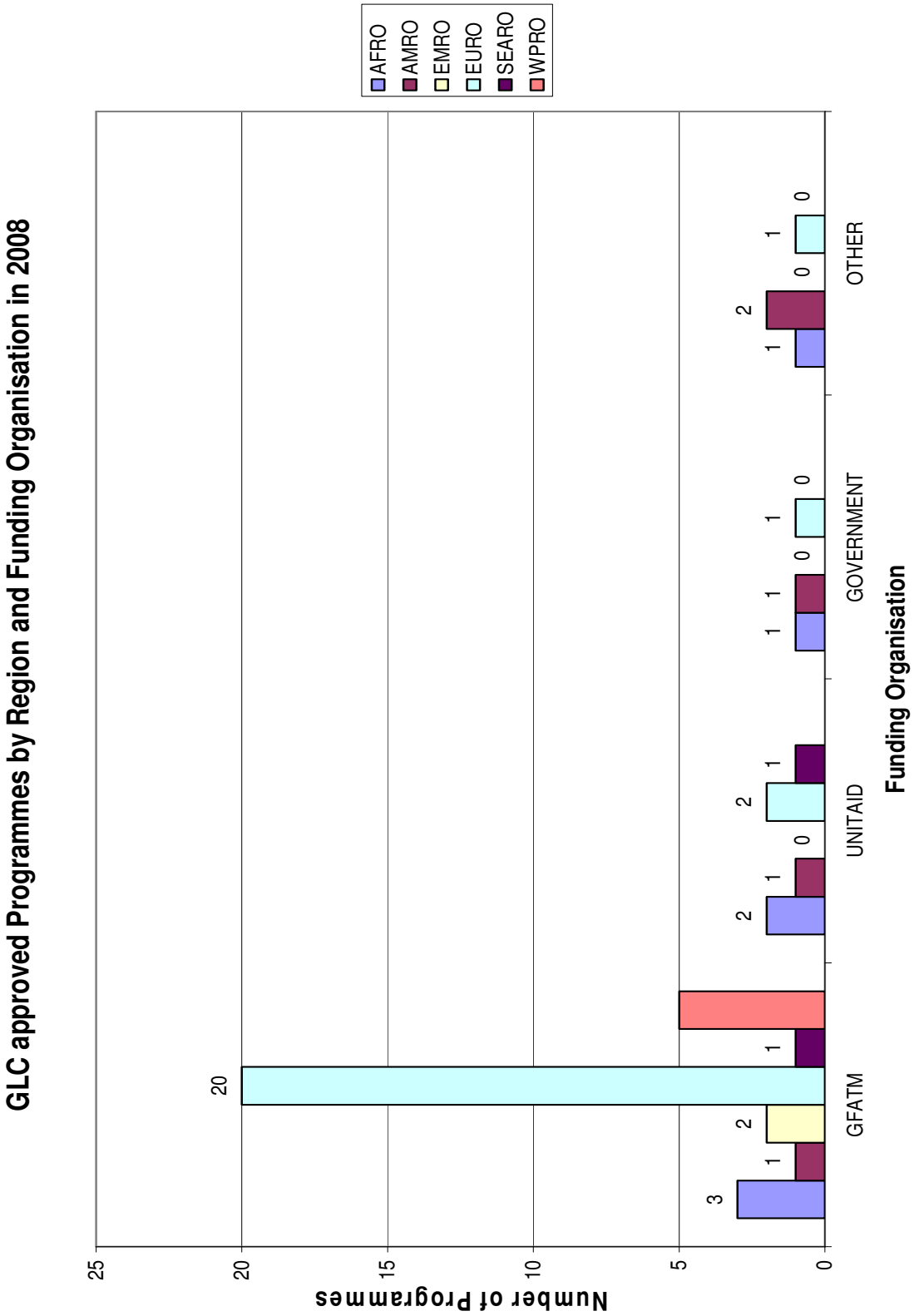
[4] Includes the increase in estimated cost for the UNITAID MDR Scale Up project and the additional 1040 patient treatments
[5] As assessed under the Procurement, Quality and Sourcing Project: Access to Anti-Tuberculosis Drugs of Acceptable Quality, which is coordinated and implemented by the WHO Department Medicines Policy and Standards/Quality Assurance and Safety of Medicines and for which GDF is a principal contributor of funds and political support.
[6] Or carry an equivalent compliancy, such as through a recognized stringent regulatory authority.
[7] Source: International Drug Price Indicator Guide 2007, http://erc.msh.org/.

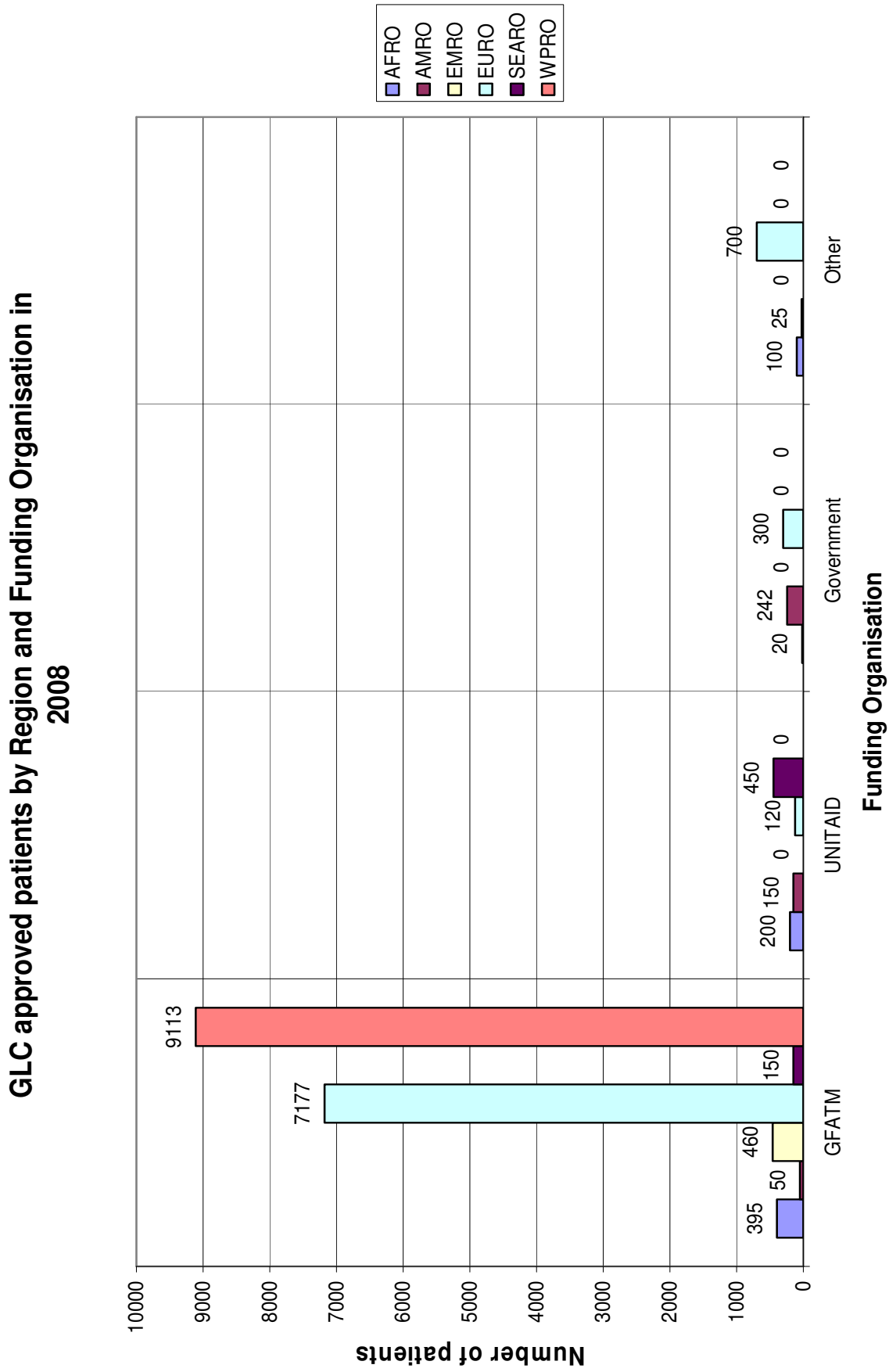
	Average number of days from order finalization to first delivery (all orders)[8]	109	107	
	Total value of requests delivered (product costs only, US$)	$9,959,424	$4,283,525	$14,242,949
	Total value of requests delivered (Global Fund orders, US$)	*$8,517,012*	*$2,716,693*	*$11,233,705*
Second Line All Grants	Number of orders placed	29	6	38
	Number of requests delivered	27	9	27
	Number of Countries placing orders	12	n/a	13
	Number of Countries receiving Deliveries	12	n/a	12
	% of requests arriving in countries on schedule	74.07%	n/a	
	Average lead time	113	n/a	
	Total Cost of all orders placed (2008)	$3,032,994[9]	$1,706,718	$1,706,718
	Total Value of all orders delivered (2008)	$2,115,238	n/a	$2,115,238
	Average total cost of a delivered request (all orders, US$)	$78,342	n/a	

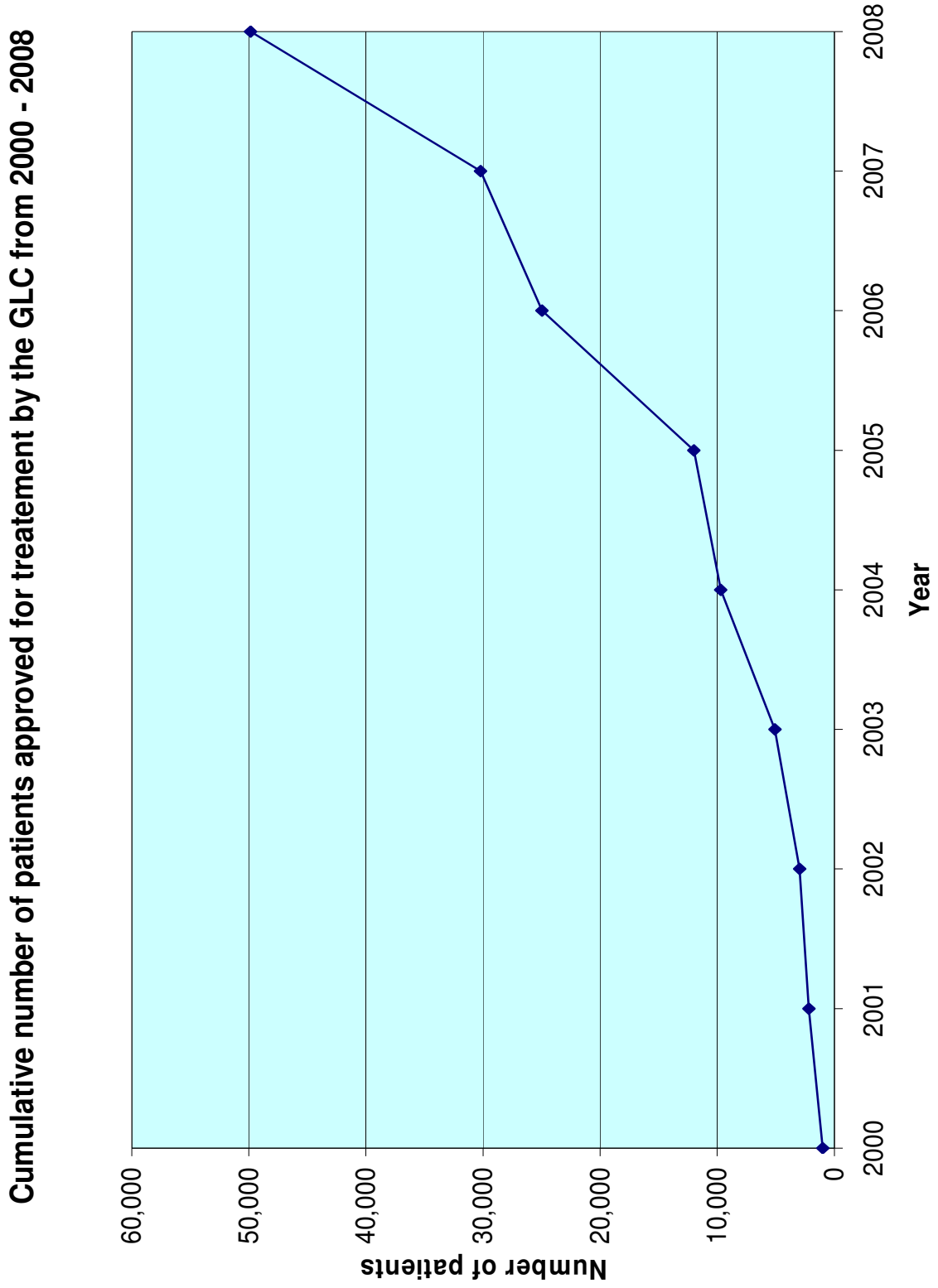
[8] It is important to note that for second line orders, projects will often place their orders in advance for delivery at a specified later date, therefore standard lead time calculations (i.e. order placed with supplier to first drug delivery) do not give an accurate representation of order production and delivery time. Information comparing actual delivery date with requested delivery date is available upon request to GDF.

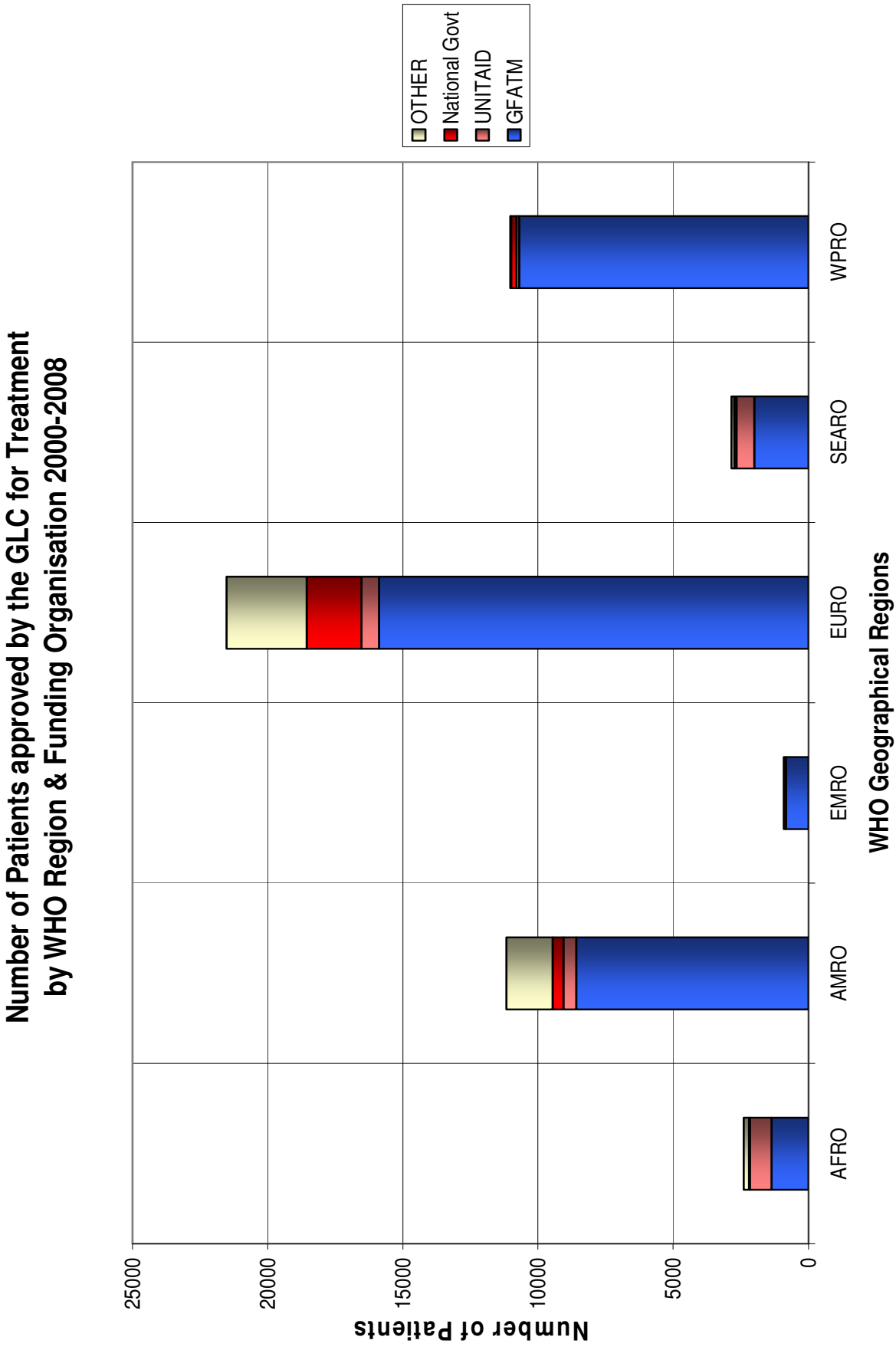
[9] Difference between this amount and amount reported on UNITAID annual report is due to several orders being identified as UNITAID orders that had been previously incorrectly identified

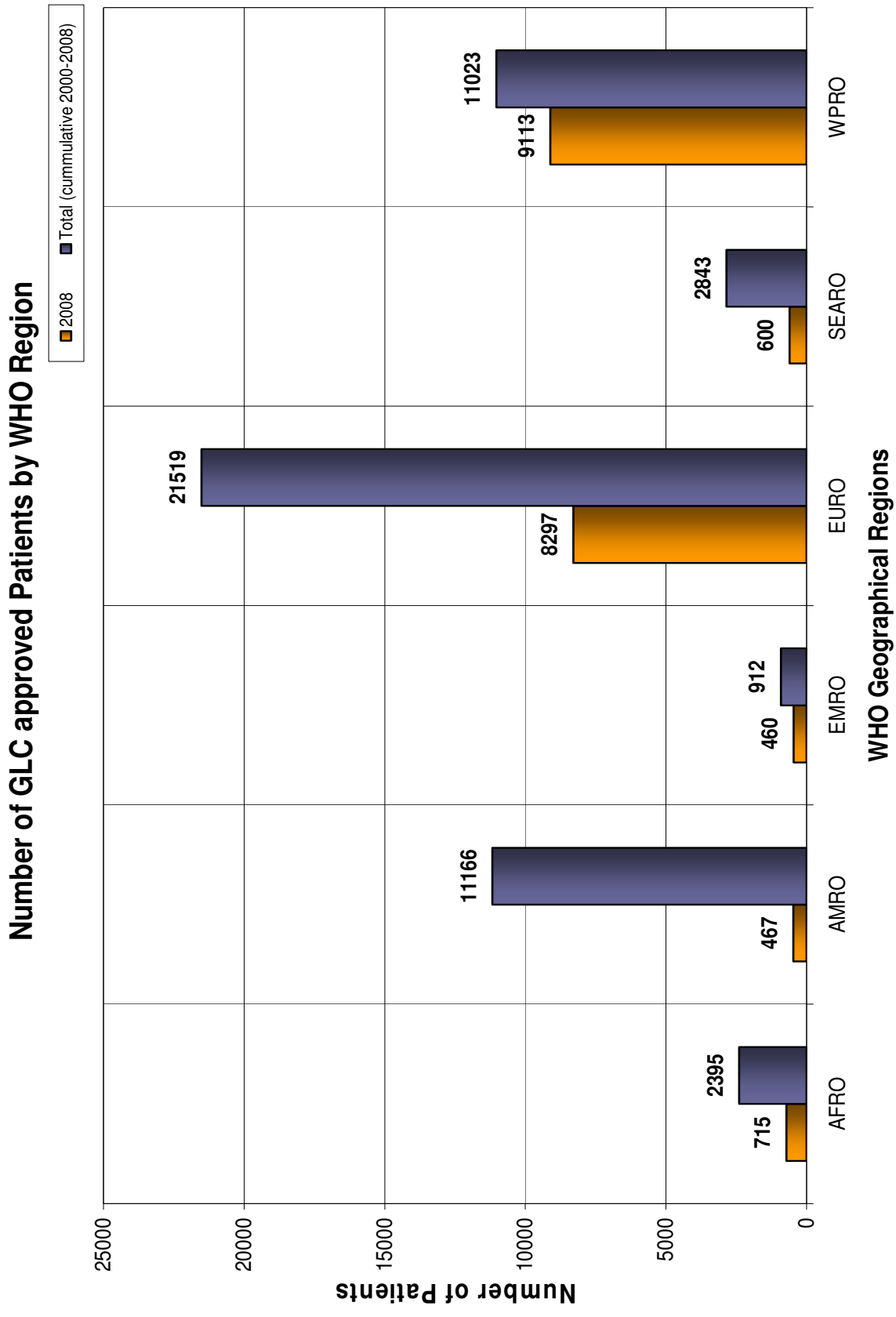
Annex 4. Graphs




GLC approved patients by Region and Funding Organisation in 2008
AFRO
AMRO
EMRO
EURO
SEARO
WPRO
Number of patients
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
9113
7177
395
50
460
150
200
150
0
120
450
0
20
242
0
300
0
0
100
25
0
700
0
0
GFATM
UNITAID
Government
Other
Funding Organisation


Cumulative number of patients approved for treatement by the GLC from 2000 - 2008
Number of patients
60,000
50,000
40,000
30,000
20,000
10,000
0
2000
2001
2002
2003
2004
2005
2006
2007
2008
Year


Number of Patients approved by the GLC for Treatment
by WHO Region & Funding Organisation 2000-2008
OTHER
National Govt
UNITAID
GFATM
25000
20000
15000
10000
5000
0
Number of Patients
AFRO
AMRO
EMRO
EURO
SEARO
WPRO
WHO Geographical Regions


Number of GLC approved Patients by WHO Region
2008
Total (cummulative 2000-2008)
25000
20000
15000
10000
5000
0
Number of Patients
715
2395
467
11166
460
912
8297
21519
600
2843
9113
11023
AFRO
AMRO
EMRO
EURO
SEARO
WPRO
WHO Geographical Regions

ANNEX 5.

GDF second-line anti-TB drugs (SLD) Information Sheet: Quality and regulatory status of SLD supplied by GDF

Quality Assurance (QA): eligibility criteria of product-manufacturer(s):

A. Manufacturing Site:

1) The site must have been inspected by WHO as a part of the WHO Procurement, Quality and Sourcing Project: Access to Tuberculosis Drugs of acceptable quality ("WHO Prequalification Programme (WHO PQ)", see http://mednet3.who.int/prequal/) and found to be operating at an acceptable level of compliance with WHO Good Manufacturing Practices (GMP) for the specific product; **OR**

2) The site must have been inspected and found acceptable for the manufacture of the specific product by a stringent national medicines regulatory authority (SNMRA) defined as either: an ICH[1] member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement; **OR**

3) The site must have been inspected and found acceptable for the manufacture of the specific product by inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)[2].

B. Product Approval:

Products shall be in compliance with national regulatory standards and

1) Products shall be pre-qualified by WHO under the WHO PQ Project; **OR**

2) Products shall be approved by an SNMRA as defined under point A 2) above, or be approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC9 No. 726/2004) or United States FDA tentative approval

In absence of a product meeting the standards B 1) and 2) above, a product may be approved by GDF under the following option:

3) Products shall be found acceptable to the GDF through an interim risk/benefit assessment process involving a Technical Evaluation Committee. Products shall be eligible for this interim process under the following conditions:

a) The Finished Pharmaceutical Product (FPP) must be manufactured at an approved site as established under Section A above.

b) A product approval as described under either points B 1) or 2) is pending, i.e. manufacturers have submitted relevant product dossiers and the dossiers have been accepted for assessment either by WHO PQ or SNMRA. Manufacturers shall commit to making their best efforts to advance their relevant product dossier in the approval process.

Approvals under point 3) shall be limited to a duration to be defined by GDF at the time of each approval. The Technical Evaluation Committee is appointed by GDF and by the WHO PQ Project in collaboration with selected other partners such as the Drug Management Sub-Committee to the Working Group on MDR-TB.

[1] International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use: www.ich.org
[2] Pharmaceutical Inspection Co-operation Scheme: http://www.picscheme.org/

The current quality and regulatory status of SLDs supplied by GLC/GDF is as follows:

Product	Description	Manufacturer and manufacturing site status	Product dossier status
MDR Am 500 mg/ 2ml 10 box	Amikacin 500mg/2ml solution for inj vial	Medochemie - Cyprus EU-GMP compliant Myland - France EU-GMP compliant	Registered in Greece (EU-drug registration requirements compliant) Registered in France (EU-drug registration requirements compliant)
MDR Cm (A) 1gr vial	Capreomycin 1gram powder for inj vial	Eli Lilly - USA FDA-GMP compliant	Registered in USA by FDA (FDA-drug registration requirements compliant)
MDR Cs 250 mg Cap 100-S	Cycloserine 250mg capsules 10 Al strip	Macleods-India WHO-GMP compliant Aspen - South Africa WHO-GMP compliant and PICs GMP compliant	Pre-qualified by WHO Pre Q Project Registered by MHRA (UK). Dossier under evaluation by WHO PQ.
MDR Eto 250 mg Tab 100 Jar	Ethionamide 250mg tablets 100 jar	Macleods-India WHO-GMP compliant	Pre-qualified by WHO Pre Q Project
MDR Km 1gr Vial 50 box	Kanamycin 1 gram powder for inj vial	Phanpharma-France EU-GMP compliant.	Registered in Lithuania, Romania and Latvia (EU-drug registration requirements compliant)
MDR Lfx 250 mg tab 100-B	Levofloxacin 250 , 500 mg tablets 100 blister	Macleods-India WHO-GMP compliant.	IDA QA and GMP, AND Drug dossiers are ready to be submitted to WHO PQ
MDR Ofx 200 mg Tab 100	Ofloxacin 200, 400 mg tablets 100 jar / blister	Macleods-India WHO-GMP compliant.	IDA QA and GMP, AND Drug dossiers are ready to be submitted to WHO PQ Project
MDR PAS Acid 4 gr 30 Sac	PAS acid sachet eq. to 4 g	PASER from Jacobus FDA GMP compliant	Registered by FDA. (FDA-drug registration requirements compliant)
MDR PAS Sodium	PAS Sodium 60% 100 g jar	Macleods - India	IDA QA WHO GMP Dossier under evaluation by WHO PQ Provisionally approved by GDF as secondary source under specific conditions
MDR Pto 250 mg Tab 100 Jar	Prothionamide 250 mg tablets 100 jar	Fatol – Germany EU – GMP compliant	Registered in Germany (EU-drug registration requirements compliant)
MDR Mxf 400 mg tab 5 tab blister	Moxifloxacin 400 mg tab	Bayer-Germany EU-GMP compliant	Registered in Germany (EU-drug registration requirements compliant)

IDA Foundation's (GDF Procurement Agent for 2nd line drugs) QA mechanism involves (i) independent assessment of GMP as per WHO's guidelines (site inspections plus desk audits); (ii) product dossier assessments for quality, safety and efficacy; (iii) verification of labeling, methods of analysis, packaging and shelf-life; and (iv) quality control testing at a WHO pre-qualified laboratory. These activities are performed by qualified experts in IDA's Quality Assurance Department.

Drug Registration for Countries Receiving SLD:

The selection of qualified GDF drugs is based on regulatory status and quality assessment of each product. GLC/GDF requests the NTP/DR-TB managers to share this status information with the National Medicines Regulatory Agency (NMRA) in order to facilitate the drug registration procedure.

The WHO PQ project is a very powerful mechanism for assuring the quality of drugs (HIV-AIDS, TB and Malaria) in international commerce and being imported into many developing countries. The inspectors and drug dossier reviewers have the highest level of expertise. All UN procurement agencies, GFATM, many international humanitarian organizations, and many national drug regulatory agencies rely entirely on the outcomes of the WHO PQ Project. NDRA can have access to the information on dossier evaluation and inspections at http://healthtech.who.int/pq/. Likewise NDRA can also communicate with WHO PQ though contact details given on its website http://www.who.int/medicines/areas/quality_safety/en/ for further queries.

In the same way, in countries with SNMRA (as defined by GDF), the highest recognized international GMP and drug registration requirements are enforced.

In addition, IDA verifies all consignments before dispatch. This includes the products, the quantities, the shelf-life, the packing, and the certificate of analysis. Analytical verification with qualified test methods by qualified laboratory is also performed randomly.

Based around the manufacturing sites and drug dossiers evaluation status given above, **GDF would strongly advise the national drug regulatory authorities to:**

* Recognize and accept outcomes from WHO PQ project
* Recognize and accept outcomes from SNMRA like EU and FDA
* Apply fast-track registration foreseen in the national pharmaceutical law and/or allow importing and distributing drugs in the country prior to registration while the registration process is being carried out.

In this way, the SLD are more rapidly available for patients in immediate need once they receive GLC approval and registration issues are not a cause for delay.

Do not hesitate to contact the GDF should you need more information/clarifications.

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Organization
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