

Pathway to Patients

Charting the Dynamics of the Global TB Drug Market



TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

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Preface

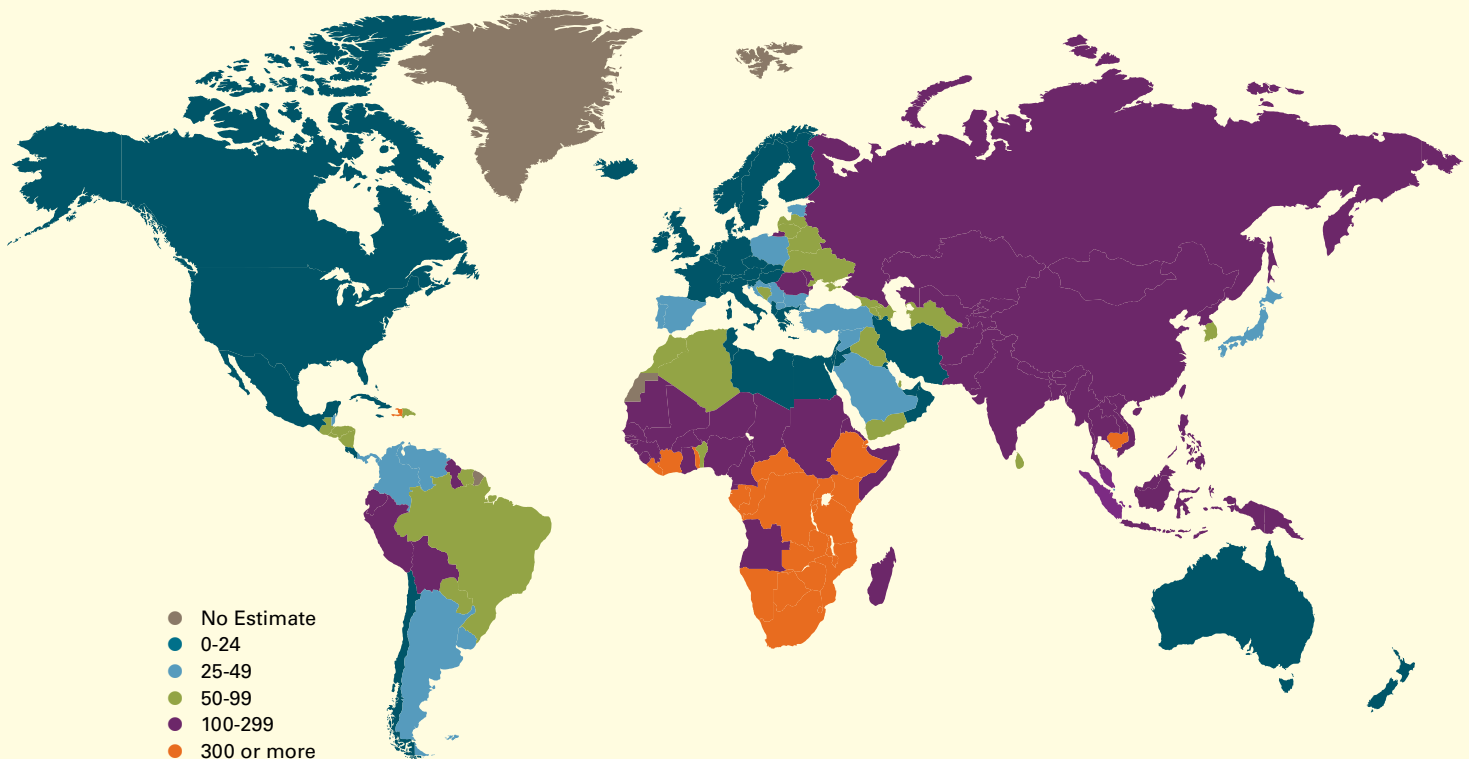
More than a century after the discovery of *Mycobacterium tuberculosis* (*M.tb*), the bacillus that causes tuberculosis (TB), and a half-century after the discovery of antibiotics to treat the disease, TB is second only to HIV as the leading infectious killer of adults worldwide.

TB kills someone every 20 seconds—about 4,400 people every day, or approximately 1.6 million in 2005 alone, according to the latest estimates from the World Health Organization (WHO).¹ It accounts for more deaths among women than all other causes of maternal mortality combined² and is the leading infectious cause of death among people with HIV/AIDS.³

The WHO estimates that one third of the world's population is infected with *M.tb*, with the greatest burden relative to population concentrated in low and middle income countries with high incidence of infection in sub-Saharan Africa, Asia and South America, as shown in Figure 1. Furthermore, today's TB epidemic is fueled by a surge in HIV-*M.tb* co-infection and compounded by the growing emergence of drug resistant strains.

Apart from its devastating health consequences, the economic impact of the disease is staggering, making TB a significant contributor to world poverty. TB is estimated to absorb US\$12 billion from the incomes of the world's poorest communities. In some countries, loss of productivity attributable to TB is in the order of four to seven percent of gross domestic product.⁴

Figure 1. Estimated Global TB Incidence (2005)



Source: *Global tuberculosis control: surveillance, planning, financing. WHO report 2007*. Geneva, World Health Organization.

¹ *Global tuberculosis control: surveillance, planning, financing. WHO report 2007*. Geneva, World Health Organization.

² Connolly M, Nunn P. Women and tuberculosis. *World Health Stat Q*. 1996;49:115-119.

³ Frequently Asked Questions About TB and HIV. World Health Organization. <http://www.who.int/tb/hiv/faq/en/>. Accessed 2/27/07.

⁴ *HIV/AIDS, Tuberculosis and Malaria: The Status and Impact of the Three Diseases*. The Global Fund to Fight AIDS, Tuberculosis and Malaria, 2005.

The current TB drug regimen, a product of the best scientific advances of the 1960s, works for active, drug-susceptible TB—as long as patients complete the six- to nine-month treatment. However, today's four-drug combination, taken ideally under direct observation by a healthcare worker or community member, is burdensome for patients and care providers alike and despite the enormous advances in provision of services over the past few years, many patients do not or cannot complete treatment.

Poor adherence and improper administration of the existing antibiotics have led to the emergence of multi- and extensively drug resistant TB strains, known as MDR-TB and XDR-TB, respectively. Further, the global HIV/AIDS pandemic is fueling an increase in TB, resulting in a dramatic rise in the number of co-infected individuals. An estimated one-third of the 40 million people living with HIV/AIDS worldwide are co-infected with TB. People with HIV are up to 50 times more likely to develop TB in a given year than HIV-negative people, and TB is one of the leading causes of death in HIV-infected people, particularly in low income countries.⁵ In sub-Saharan Africa, up to 80 percent of tuberculosis patients are also HIV-infected.⁶ Unfortunately, the current TB drug regimen is not compatible with certain common antiretroviral therapies used to treat HIV/AIDS.

Critical to fighting this ancient disease is the development—and subsequent adoption—of affordable, new, faster and simpler drug regimens. After almost half a century of virtual inactivity, TB drug development has resurged. Bolstered by new scientific information on the bacillus, transforming international funding from philanthropic sectors and government donors, and the appearance of innovative business models designed to breach the drug development gap, the current global TB drug pipeline is the largest in history.

Experience has demonstrated that attrition rates are very high in drug development and it is expected that TB drugs will be no exception. However, the strength of the portfolio underscores the fact that even more new TB drug candidates and novel drug regimens are likely to be forthcoming within the next five to ten years.

Experience has also demonstrated that the uptake of innovation is a process that requires understanding of market forces, distribution channels, purchasing power and myriad other considerations. The promising new TB cures will be ineffective and the resurgent movement for TB drug development will have failed if the new treatments do not reach patients.

In 2006, the Global Alliance for TB Drug Development (TB Alliance) commissioned *Pathway to Patients: Charting the Dynamics of the Global TB Drug Market*. The study is the first comprehensive analysis of how today's TB drugs reach patients on a global scale. It includes an assessment of ten strategically selected countries—Brazil, China, France, India, Indonesia, Japan, the Philippines, South Africa, the UK and the US—as well as an appraisal of today's worldwide TB drug market value. This report is an overview of the study's findings and summarizes the pricing, purchasing, procurement and distribution mechanisms for first- and second-line TB treatments in these countries. In addition, the study updates the original global drug market assessment carried out by the TB Alliance in 2001 in *The Economics of TB Drug Development*⁷.

The research for *Pathway to Patients* was conducted in partnership with IMS Health, Inc., a global strategic consulting group focused on the pharmaceutical and health care industries. The project was financed by a grant from the Netherlands Ministry of Foreign Affairs' Department of Development Cooperation (DGIS) and with the support of the Bill & Melinda Gates Foundation. A compendium of findings, detailed description of methodology, and analysis of each country studied can be found online at www.tballiance.org.

5 *Frequently Asked Questions About TB and HIV*. World Health Organization. <http://www.who.int/tb/hiv/faq/en/>. Accessed 2/27/07.

6 Reid A, Scano F, Getahun H, et. al. Towards universal access to HIV prevention, treatment, care, and support: the role of tuberculosis/HIV collaboration. *Lancet* 2006; 6: 483-495.

7 *Executive Summary for The Economics of TB Drug Development*. Global Alliance for TB Drug Development. October, 2001.

Introduction to the Project

Of the ten countries studied, six were chosen from among the 22 identified by the WHO as “high burden” nations: Brazil, China, India, Indonesia, the Philippines, and South Africa. Together, these countries carry approximately 50 percent of the world’s TB burden.⁸ The project also encompassed four high income countries, France, Japan, the UK and US. Although the latter have a low burden of disease, they represent a significant value of the TB market because of higher cost of treatment. For the study, research on Indonesia and Japan was limited to determining market value and did not examine procurement and distribution.

The research methodology included both qualitative and quantitative components. Qualitative primary and secondary data were used to map: 1) the flow of TB medicines from supplier to patient; 2) the selection process for suppliers; and 3) the role of public and private payers for first- and second-line TB medicines. In-depth quantitative analysis provided the basis for understanding the market dynamics.

It should be noted that the study did not seek to review or address the quality of TB treatment or the quality of procurement and distribution in any of the countries studied.

Key Findings

The Role of Global Procurement Agencies

A number of organizations known as procurement services agencies (PSAs) exist at the global level to assist countries and/or organizations in supplying drugs to their respective TB programs. *Pathway to Patients* studied the two PSAs engaged in procurement activities in the high burden countries selected: the Stop TB Partnership’s Global TB Drug Facility (GDF) and Green Light Committee (GLC).⁹

GDF

The Stop TB Partnership launched the GDF in 2001 to provide grants and a direct purchasing option to governments and NGOs for high quality, low cost drugs for treatment of drug susceptible disease (first-line treatment). In the first five years, the GDF supplied 4.6 million treatment courses through grants and 2.7 million through direct procurement in 71 countries, at an average cost of US\$15 per person.¹⁰ As shown in Figure 2, the GDF supplies first-line TB drugs to 13 of the 22 WHO-designated high burden countries. However, of the countries for which procurement was studied, only India and the Philippines currently use the GDF, and even for those countries, first-line drugs are also sourced through public tender processes.

GLC

The GLC serves as a global supplier of MDR-TB drugs. The GLC assesses applications, determines whether a particular treatment program is in compliance with WHO guidelines, and upon approval, allows access to concessionally-priced anti-TB drugs. In 2005, approximately 9,000 patients received drugs through the GLC, with treatment regimens ranging from US\$500–2,600 per patient, depending on resistance patterns.

Figure 2. WHO 22 High Burden Countries Based on GDF Supply

1. India	12. Russian Federation*
2. China*	13. Vietnam*
3. Indonesia	14. Tanzania
4. Nigeria	15. Brazil*
5. Bangladesh	16. Uganda
6. Pakistan	17. Thailand*
7. Ethiopia*	18. Mozambique
8. South Africa*	19. Zimbabwe*
9. Philippines	20. Myanmar
10. Kenya	21. Afghanistan
11. DR Congo	22. Cambodia*

* Do not purchase TB drugs or receive grants of drugs through the GDF

⁸ *Global tuberculosis control: surveillance, planning, financing. WHO report 2007.* Geneva, World Health Organization.

⁹ In early 2006, GDF announced that it would converge with GLC. Procurement functions of GDF and GLC already have been combined. Plans to combine their application, review, monitoring, and evaluation functions are currently underway.

¹⁰ *GDF Facts & Figures.* Stop TB Partnership, Global TB Drug Facility. http://www.stoptb.org/gdf/whatis/facts_and_figures.asp. Accessed 2/28/07.

Figure 3. National TB Control Program Responsibilities

LEVEL OF NTP	DESCRIPTION OF RESPONSIBILITIES
Central TB Division	<ul style="list-style-type: none"> • Sets priorities and guidelines for National TB Control Program • Allocates funding to states • Sets program budget guidelines • Collects and reports epidemiological data
Provincial/State TB Division	<ul style="list-style-type: none"> • Sets tactical plans for program within the state • Sets program budget • Collects and reports epidemiological data to central division
District/Local Office	<ul style="list-style-type: none"> • Trains and supervises healthcare facilities in TB control • Collects and reports epidemiological data to provincial/state division
Facilities	<ul style="list-style-type: none"> • Administers care to TB patients • Collects patient and reports to district/local program office

By November 2006, 51 projects in 40 countries had been approved by the GLC for the treatment of up to 25,000 MDR-TB patients over the next three years.¹¹ Of the countries included in the in-depth study, only the Philippines currently uses the GLC, with treatment planned for 2,500 patients over a five year period (2006–2010).

TB Control in the Context of National Healthcare Systems

All countries studied have a national, publicly-financed healthcare program through which a portion of or all drugs and medical services are provided free of charge to at least a segment of individuals and often to all citizens. Of those healthcare systems studied, most have national TB control programs through which TB patients may be treated at a public facility.

In high burden countries, TB control is administered by a dedicated department within the Ministry of Health or equivalent agency. The research showed that TB control in the public sector is typically administered through a vertically structured program, with responsibilities defined at national, state or provincial, and local or municipal levels. Figure 3 provides an overview of the responsibilities typically associated with each such level. In contrast, in France, the UK, and the US, the national TB program is part of the infectious disease section of the respective public health authority.

TB Healthcare Service Provision

All countries studied have a public sector in which patients can receive diagnostic and treatment services. In Brazil and South Africa, most TB treatment is provided by the government. In contrast, in India and the Philippines, despite significant public sector programs, many patients prefer to seek diagnosis and treatment in the private sector for reasons that include perceived quality of care and maintenance of anonymity. In these countries, the private sector accounts for 70 percent or more of the TB drug sales and a sizeable amount of TB care. In China the private sector is primarily used for treatment of drug resistant disease. The estimated market value section of this report (page 7) provides a breakdown of drug procurement in the private vs. public sector in select countries.

Private sector practices in TB pose a number of challenges to the public sector program. For example, patients entering the private sector may not be reported into the national TB control program making it difficult to estimate the TB burden and track success in diagnosing and treating patients. Also, physician regimens differ from national guidelines and in many instances, less effort is placed on treatment adherence. To address quality of care in the private sector, India and the Philippines have piloted “public-private mix” programs in an effort to reach more people with appropriate treatment and help provide an incentive to the private sector to adhere to the nationally approved regimen. Under this model, physicians who suspect a patient has TB or initially diagnose a patient with TB can refer the

11 Stop TB Working Group on MDR-TB–Home. Stop TB Partnership. http://www.stoptb.org/wg/dots_plus. Accessed 2/28/07.

patient to the public sector for further diagnosis and free treatment, or may continue to treat the patient him or herself, with drugs provided at no cost or subsidized by the government.

Payment for Drugs and Services

In all high burden countries studied, treatment for drug susceptible disease is free of charge to patients in the public sector. The treatment costs vary significantly by country based on supply sources used and the process by which drugs are procured. Price is determined as part of a national public tender process in these countries, as well as in France and to some extent the UK.

At present, of the high burden countries studied, only the governments of Brazil and South Africa are providing drugs for MDR-TB universally. Prices for these drugs are negotiated directly with suppliers. In China, India and the Philippines, pilot programs for MDR-TB are underway. High income countries provide treatment for MDR-TB patients as an integrated component of the general healthcare system. In France and the UK, the treatment of these patients is financed by the public sector. In the US, there is no separate or centralized funding for the treatment of either drug susceptible or MDR-TB. Rather, TB treatments are funded by both public and private payers (e.g. Medicare, Medicaid, private health insurance). For the uninsured, funding may be provided through either the federal, state or local health systems or through patient assistance programs sponsored by pharmaceutical companies who manufacture the drugs.

Figure 4. Public Sector Procurement Mechanisms for First-line and Second-line TB Drugs in High Burden Countries Studied

COUNTRY	PUBLIC TENDER ¹²	GDF	GLC
Brazil ¹³	●		
China	●		
India	●	●	
Philippines	●	●	●
South Africa	●		

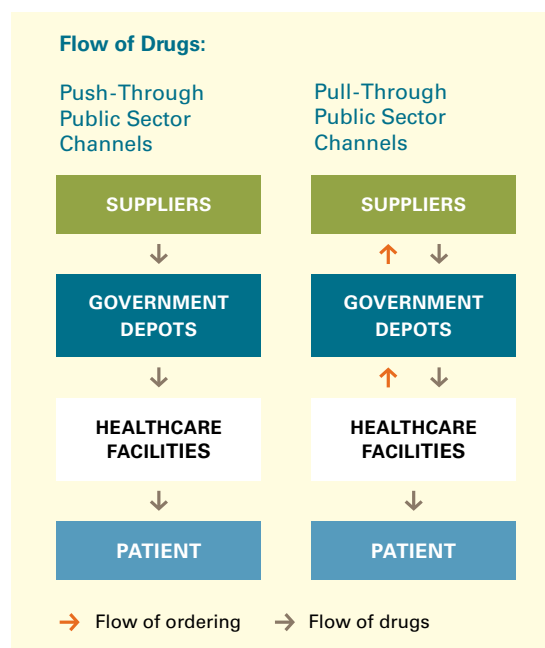
Procurement and Distribution of TB Medicines in High Burden Countries

The public markets in the high burden countries studied, with the exception of the Philippines, procure most or all of their drugs through a bid and tender process. For second-line products, there may also be a direct negotiation between the governments and suppliers (see Figure 4). The national TB control program (or a related agency within the government) determines the approximate volume of drugs that are needed by the public sector for the period of the tender contract, requests bids from drug manufacturers, and selects suppliers who agree to provide drugs for a preset period of time, at a price determined in the bidding process.

Although tenders are open to both national and international suppliers, nearly all of the countries included in the study prefer to source their drugs from locally-based companies when possible. Only two of the countries studied, India and the Philippines, use the GDF. In India, the GDF supplies approximately half of the drugs used by the public sector and in the Philippines, the GDF supplies all treatments for smear positive and re-treatment cases.

For second-line drugs, the public programs in Brazil and South Africa procure locally or through direct negotiation with suppliers and do not use the GLC.

Figure 5. Flow of Drugs through the Public Pull vs. Push Systems in High Burden Countries



¹² For some second-line drugs, procurement is done through direct negotiation with suppliers rather than through a tender process.

¹³ In 2005 due to internal manufacturing problems, Brazilian national suppliers were unable to meet the total demand for first-line TB drugs, and were assisted by PAHO. Generally, Brazil produces 100 percent of its national drug supply.

Although patient numbers are limited, the Philippines is currently using the GLC to supply drugs for MDR-TB treatment programs.

TB drugs purchased in the public sector tend to flow through a series of public depots or warehouses before reaching the facilities that administer them to patients. The frequency with which drug orders are submitted and shipped varies by country. The countries studied follow one of two models of distribution: the push system or the pull system.

Figure 5 on the previous page represents how drugs are ordered and distributed in the public sector through the push and pull systems. Under the push system, drugs are ordered by one central agency/division and then “pushed” or delivered at regular intervals to other parts of the supply chain. This system is found in China where most drugs are ordered centrally and delivered at pre-determined intervals to depots and facilities.

Brazil and South Africa operate pull systems, where the flow of drugs is driven by orders from depots and/or facilities further along the supply chain. In these countries, bulk supplies of drugs are ordered by regional depots and held until they are requested by facilities. Orders may vary widely in size and frequency, depending on the needs of the facility or depot. India and the Philippines have both push and pull components.

Procurement and Distribution of TB Medicines in High Income Countries

In the high income countries studied, financing of TB drug treatment follows the same financing patterns of other drugs. Thus, in France and the UK, the public sector finances the purchase of most TB drugs. In the US, the private and public sectors play a role.

This distribution model is primarily a pull system, as the volume and frequency of drug orders is determined on a real-time basis and surpluses are kept at small levels, if at all. TB drugs flow through the same channels as any other drugs: from manufacturers to wholesalers to facilities or retail pharmacies, and finally to patients. In the US, some states also use a push system, with the state providing free supply and distribution of drugs to regional or local health units.

TB Drug Market Value Estimates

National Estimates

For the ten countries studied, public and private sector value data for first- and second-line drugs were determined using IMS and program data.

The value of the public markets was in most cases sourced directly from discussions with stakeholders—usually government officials or key funders— or from financial reports issued by national TB control programs. Private sector figures were sourced from IMS Health databases and segmented by product into the first- and second-line markets and adjusted, where possible, using prescription data.

National TB drug market value estimates for each of the countries studied are illustrated in Figures 6 on the following page.

Global Estimate of the First-line Drug Market

A key objective of the study was to collect sufficient data to project a global estimate of the market for first-line TB drugs, based on the value of the TB drug market in each of the countries studied. As noted earlier, the six high burden countries studied represent approximately 60 percent of TB disease in the 22 high burden countries and 50 percent of the total global TB burden.

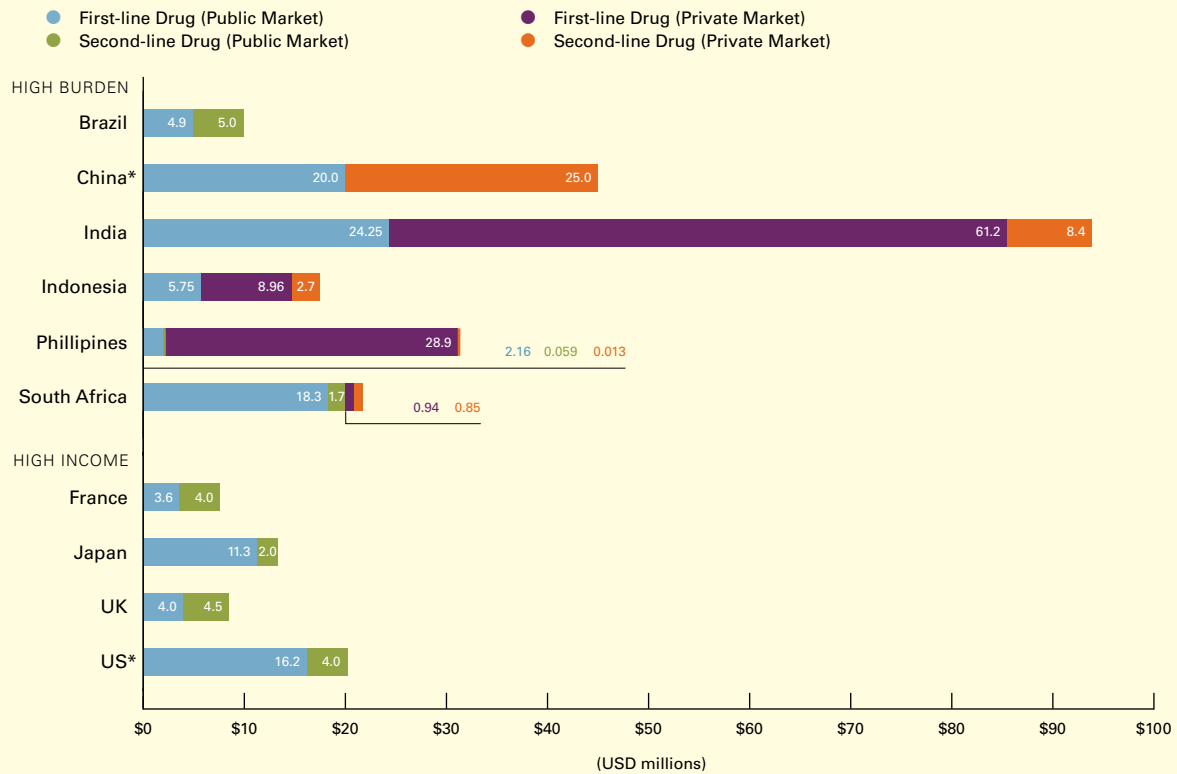
Researchers were able to extrapolate the first-ever estimate of the global market based on original research by using the data of the countries studied to yield the following projections:

1) A low end estimate, based on DOTS notification rates (actual number of cases reported by DOTS programs each year) and a range of actual and average price per patient regimen costs, suggests that the value of the global first-line market is between **US\$261M–316M**.

2) A high end estimate, based on the WHO’s global incidence figures (total projected number of new cases per year) and a range of actual and average price per patient regimen costs, suggests that the value of the global first-line market is between **US\$310M–418M**.

Assuming that current case notification rates do not always reflect the full number of patients being treated, and that incidence rates reflect the absolute maximum number of patients that can be treated, the overlap of the two ranges is the closest estimate of

Figure 6. First- and Second-line TB Drug Market Value by Country



* Although exact figures are unknown, the majority of first-line treatment is financed by the public sector. In the US, this is also true for second-line treatments.

the actual first-line market, indicating that the total value of the global market for first-line TB drugs is approximately US\$315M (see Figure 7 on the following page).

For more information about the specific methodology used to determine the market estimates for each country and the global estimates, including individual drug cost figures and a list of the countries included in the global extrapolation, a separate methodology document is available online at www.tballiance.org.

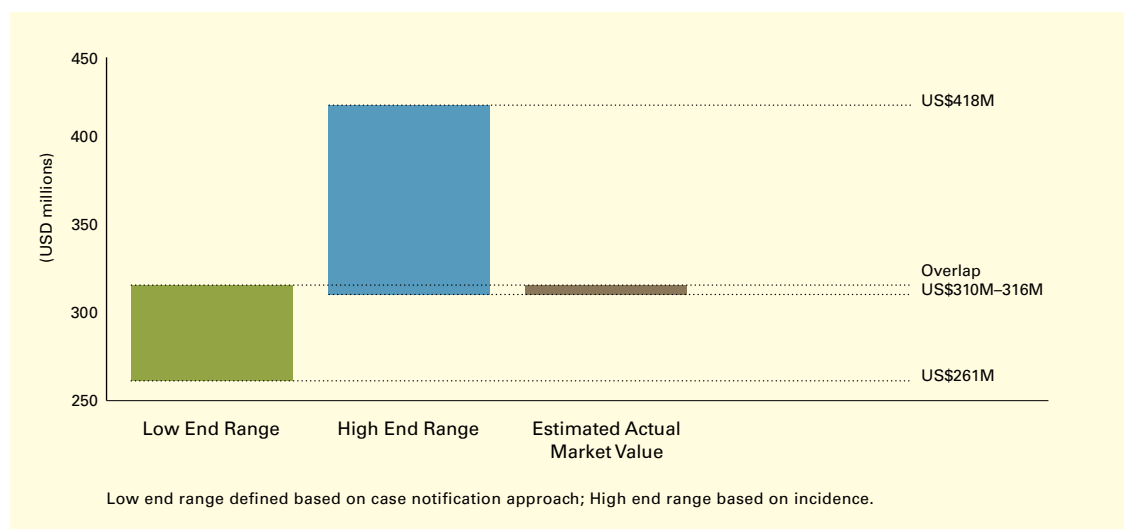
The Second-line Drug Market

The study found that a number of factors prevent making a similar, global estimate of the second-line TB drug market. According to the Stop TB Partnership’s Global Plan to Stop TB 2006–2015,¹⁴ less than two percent of estimated culture positive MDR-TB patients are treated appropriately. Cases of MDR-TB are not consistently reported, particularly

if they are not treated in the public sector. There are a number of potential treatments included in second-line regimens, and there is variance in prescribing practices, length of regimen, as well as adherence rates. Similarly, costs also vary dramatically across countries. Therefore, the researchers felt it is inappropriate to apply the methodology used to project the first-line global estimate to a second-line worldwide estimate.

However, looking only at the ten countries studied, the research found that the estimated value of the second-line TB drug market in those countries is approximately US\$54M.

14 Stop TB Partnership and World Health Organization. *Global Plan to Stop TB 2006-2015*. Geneva, World Health Organization, 2006.

Figure 7. Global Estimate Ranges of First-line TB Drug Market

Predicting Future Market Dynamics

Understanding the structure of the TB drug market, including procurement and distribution systems in high burden countries, is essential for planning the introduction of new TB drug regimens.

Potential Market Changes

This study provides in-depth insights into issues that affect the dynamics of the TB drug market today and helps map factors that will have direct and indirect impact on these dynamics between now and the time novel drug regimens are approved and ready for introduction into the global marketplace. The analysis also suggests the need for additional research into a number of evolving factors that may alter the flow of TB drugs, highlighting that a better understanding of all of this closer to the new products roll-out would facilitate adoption of and access to new TB drugs when they become available.

The Global Plan calls for expanded, equitable access for all to quality TB diagnosis and treatment by 2015. Therefore, efforts undertaken over the next decade to achieve the Global Plan, including the introduction of new tools to diagnose, treat and prevent the disease, along with policy and funding considerations, are expected to increase significantly the number of patients being treated for TB.

New Diagnostics

New, faster and more reliable diagnostic tools for TB are in the pipeline, and should begin to enter the market over the next several years. The Global Plan calls for point of care diagnostics by 2010 that will allow rapid, sensitive and inexpensive detection of active TB. Two years later, Stop TB envisions a diagnostic toolbox that will accurately identify people with latent TB infection and those at high risk of progression to disease. New diagnostics, once developed, should lead to increases in case finding that will result in an increase in demand for treatment.

New Drugs

The goal of the Global Plan is to have a new short (one–two months) TB regimen(s) by 2015. A number of trials are currently underway that could, by 2010, potentially shorten the regimen to three–four months. Shortened treatment with novel drugs offers the potential to enhance patient adherence, decrease default rates, curtail costs to the healthcare system and patients, and substantially improve outcomes for those infected, especially for patients co-infected with HIV and TB. If realized, these advantages are expected to increase the need and demand for new TB drugs.

The expansion of drug resistant TB worldwide is affecting market dynamics. This is expected to increase because countries are beginning to include treatment of MDR-TB and XDR-TB as part of their national TB control programs. Expanding the coverage of drug-resistant TB will increase the market demand for second-line drugs.

Patient access to novel therapies will require national and international adoption of new treatments and extensive “retooling” of TB programs to accommodate changes in the regimen. A number of elements, including cost, availability and ease of administration will have a direct impact on adoption of new therapies. Fully understanding these and other factors will be critical for implementation of new shorter regimens worldwide.

New Vaccine

While numerous factors lead to the potential of increased numbers of patients being treated, resulting in larger demand for TB drugs, others could lead to a longer-term *decrease* in market demand. Specifically, the Global Plan calls for a new, safe, effective and affordable vaccine to be available by 2015. The current vaccine is 85 years old, works only in children, and is not always effective. A new preventive vaccine that works to protect all age groups has the potential, if widely adopted and used, to provide a positive impact on TB control and, in the long-term, a significant reduction in the number of those requiring treatment.

It will be important to understand the potential effects of a successful vaccine on TB drug demand and the market. Further study of this interface will be possible when more is known about the profile of a new vaccine.

Policy Influences

Policy changes have the potential to increase the number of patients treated, thereby affecting the market dynamics and highlighting the need for close monitoring of these changes in the years ahead. An example is China’s recent decision to include treatment of smear negative patients as a part of its

national TB control program, which adds patients and increases the amount of drugs needed by the public program. Similarly, the expansion of public sector funding for treatment of drug resistant TB in markets like India, China and the Philippines, albeit slow, will increase the number of patients receiving second-line drugs and, over time, will change the value dynamics of that market.

In the past 15 years, public sector TB programs have dramatically expanded in many high burden countries. In those countries with large private sector markets, like India and the Philippines, there is a slow trend of patients moving from private to public sector treatment, largely due to government implementation of WHO-recommended “public-private mix” programs. This could result in a decrease in the value of the private market, but an increase in value of the public tender market.

Funding Influences

With widespread commitment to the Global Plan and the introduction of new financing mechanisms and commitments by the UN, G8, and donor and high burden countries, it is expected that TB control programs will continue to expand and strengthen over the next ten years. However, the extent to which the drug market responds to this expansion will depend on a number of variables.

In the countries studied, most funding used for TB drugs, whether from the public or private sectors, comes from domestic sources. Some high burden countries, however, are dependent on external donor funding to enhance their national commitment, especially for second-line drugs and pediatric TB medication. New funding schemes, such as the Global Fund for AIDS, TB and Malaria (GFATM) and UNITAID, an international drug and diagnostics purchase facility, may offer increased access to second-line TB medications over time. Thus, markets — especially for second-line drugs — will continue to be susceptible to trends and changes in funding.

Conclusions

Pathway to Patients studied the TB drug marketplace in ten countries, providing a comprehensive understanding of country-specific data and an analysis of procurement and distribution systems in eight of these countries and at the global level. The study points to the variability of the market dynamics among the countries studied, the complexities of the issues faced, and the fragmented nature of the market.

The Market

The study's current global estimate for first-line TB drugs is approximately US\$315M per year, including high income country sales. This projection is consistent with that offered in the 2001 study *The Economics of TB Drug Development*¹⁵ which, using a different methodology, estimated the first-line market in 2001 at approximately US\$350M.

While the total market estimate is not inconsiderable, the TB marketplace is highly fragmented because it is shared by more than four drugs and a multiplicity of suppliers. This fragmentation is not likely to change. First, successful treatment of TB will most likely require a combination therapy. Second, as the study suggests, domestic drug production facilities may be integral to market entry for new TB drugs in most countries studied and likely in others.

At present, there is also a limited commercial market for second-line TB drugs. While the MDR- and XDR-TB markets have revenue-generating potential, current access in most countries is primarily restricted to the private sector, with prices that severely limit access for most patients with drug resistant TB. Tapping this market would require a significant expansion of public sector treatment programs, as well as government- or donor-sponsored purchase and procurement.

In the high income countries studied, the total TB market is relatively small, with pricing and procurement following the same pricing systems as other pharmaceuticals. France, Japan, the UK and the US combined —accounting for 61 percent of the total global pharmaceutical market¹⁶—purchase less than US\$50M worth of TB drugs.

Lessons Learned from High Burden Countries

The study suggests that careful planning will be needed to accelerate the adoption of any new TB drug regimen in the high burden countries. Research confirms the preference of many countries to purchase TB drugs directly from local suppliers and not from the global marketplace. Although the GDF services a number of countries, especially those that lack local manufacturers or quality assurance capacity, most purchasers for the public sector markets studied show a strong preference for procurement from domestic manufacturers. It will be essential to research this issue further, including other high burden countries, before developing roll-out plans for new TB drugs.

The study also suggests that the launch of any new drug regimen will require a phased roll-out in high burden countries. Drug approval by regulatory authorities is only the first step toward adoption. The national TB program must then decide if it will include the new therapy as part of the treatment regimen. Thus, access to public sector markets will require an understanding of the processes by which new regimens are adopted by national TB programs as well as the public tender systems and their requirements.

Even after adoption, national roll-out leading to actual patient access will take time because countries will need to understand the impact of a new regimen on service delivery and existing supply. Also, buffer stocks of existing medications must be exhausted from both the GDF and national stores. Planning for appropriate production will require an understanding of how long it would take post-approval for high burden countries to implement a change in therapy. Collaboration with disease control programs and donor agencies which have worked on supply chain issues in other areas, such as malaria and HIV, would be helpful in such planning.

Lessons Learned from High Income Countries

TB is detected throughout the high income countries studied, although most diagnosed and treated cases are concentrated in the major cities. In these economies, a number of medical specialties and subspecialties treat TB, with physicians deciding

15 *Executive Summary for The Economics of TB Drug Development*. Global Alliance for TB Drug Development. October, 2001.

16 IMS Knowledge Link. <http://www.imsknowledgeink.com>.

which treatment regimens to use. Combined with other factors, this dynamic suggests that new TB drugs and regimens will require an awareness-building campaign and/or substantial marketing efforts to reach these doctors.

Summary Observations

Although this study found some similarities across markets, the critical finding with the supply chain for TB drugs was the variability by country. There has been a recent call for a global “infomediary” to gather and organize market data for low and middle income countries, across disease areas, and act as an intermediary between those who supply the information, such as national TB control programs, and those who want the information to assist suppliers with demand forecasting, reduce delays and ensure consistent supply.¹⁷ This research suggests that a global “infomediary” could be extremely helpful to the development and roll-out of new TB drugs, by providing efficient and cost-effective information sharing.

This study provides unique insight into the complexity of today’s global TB market. Just as research and development into new compounds requires many stages before a drug is ready for regulatory approval and use, preparing the world for rapid universal adoption and use of new TB treatments will require the understanding of market dynamics, perceived benefits of the new regimens, manufacturing and supply chain issues, operational changes necessitated by new therapies, donor policies, price elasticity of demand and other attributes that would justify the change in treatment regimen.

Given the market intricacies revealed in this research, it is safe to conclude that providing the proper pathway for a new generation of faster and easier-to-use TB drugs to reach the patient will require a targeted and informed country-level and global strategy.

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¹⁷ Center for Global Development, Global Health Policy Research Network. *Consultation Report of the Global Health Forecasting Working Group*. February, 2007.



TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

About the Global Alliance for TB Drug Development

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, product development partnership accelerating the discovery and/or development of new TB drugs that will shorten treatment, be effective against susceptible and resistant strains, be compatible with antiretroviral therapies for those HIV-TB patients currently on such therapies, and improve treatment of latent infection.

Working with public and private partners worldwide, the TB Alliance is leading the development of the most comprehensive portfolio of TB drug candidates in history, and is committed to ensuring that approved new regimens are affordable, accessible and adopted.

The TB Alliance operates with the support of the Bill & Melinda Gates Foundation, Irish Aid, the Netherlands Ministry of Foreign Affairs (DGIS), the United Kingdom Department for International Development (DFID), and the United States Agency for International Development (USAID).

For more information on TB drug development and the TB Alliance, please visit www.tballiance.org.



TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT



80 BROAD STREET
31ST FLOOR
NEW YORK, NY 10004
USA

TEL: +1 212 227 7540
FAX: +1 212 227 7541

www.tballiance.org