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Marking up the medicine

Robert Matíru, of the WHO's Global TB Drug Facility, outlines how the challenges of accessing anti-TB treatment are being confronted

In January 2006, the Stop TB Partnership introduced the Global Plan to Stop Tuberculosis (TB): 2006-2015, which outlines the actions and resources needed to reduce TB incidence, prevalence and deaths in line with the Millennium Development Goals (MDGs). A fundamental aim of the global plan is to expand equitable access to affordable, quality assured anti-TB medicines, and contribute to the development of sustainable TB drug management capacity for countries in need. A principal tool developed by the Stop TB Partnership to achieve this goal is the Global Drug Facility (GDF). Launched in 2001, the facility, which is housed and administered by the World Health Organization (WHO), has greatly improved access to quality assured, preferentially priced anti-TB medicines, and in particular fixed-dose combinations (FDCs).

Improving access, pricing, quality and drug management capacity

Through its Grant and Direct Procurement Services, the GDF has provided 14 million life-saving anti-TB medicine treatments to over 90 countries, mostly in the form of FDCs. Its anti-TB medicine supplies reach approximately 30% of the TB patients in the public sector of low and lower middle income countries, including in many of the countries considered to have the highest burden of TB. Moreover, the facility has secured competitive prices for quality assured anti-TB medicines through the use of global tendering mechanisms, pooled demand, and standardisation of product selection and packaging. At its launch, GDF's prices for anti-TB medicines were, on average, one-third less than previous international tenders. Today its prices still remain the most competitive in the market for the standards of quality offered, and by publishing its prices in the public domain, the GDF has fostered transparency and global awareness of the pricing of anti-TB medicines.

Access and price have been fundamentally wedded to the facility's objective of promoting quality assurance of TB medicines. To this end, it has provided funding and technical support to the WHO's Prequalification Programme. GDF itself requires that all the anti-TB medicines that it supplies are pre-qualified under the programme or approved for supply for an interim period through an independent expert committee convened by the WHO. It is difficult to measure the number of lives saved by this emphasis on quality assurance. Its importance is unequivocal, however, when measured against overall statistics: countries in Africa and parts of Asia and Latin America, where regulatory and legal oversight is weakest, have areas where more than 30% of medicines on sale may be counterfeit or sub-standard.

Beyond the supply of anti-TB medicines and related health products, GDF has also played a crucial role in providing or brokering technical support for drug management, since shortages of anti-TB medicines frequently result from insufficient capacities within a country to plan, procure or manage medicines supply.

Situated in the broader context of global TB control, what do the above achievements mean? International targets for TB control set for 2005 were almost met, with a global (average) case detection rate of 60% and a treatment success rate of 85% achieved (compared to the targets of 70% and 85% respectively). GDF certainly played a crucial role in contributing to the latter through its facilitation and catalysis of anti-TB medicines access, though it must be stated that the facility is only one of several key initiatives of the Stop TB Partnership that has contributed to the overall progress in TB control made to date.

While this milestone represents a significant step forward on the road to realising the MDG targets as

they relate to TB control, albeit marked with regional and national disparities, the challenges that remain are enormous. These obstacles obviously go beyond the key area of scaled up and sustainable medicines access, but the ones germane to this issue I shall highlight.

The access challenges ahead

In terms of medicines supply, the key challenges that the Stop TB Partnership, including GDF, will face in meeting projected targets for ensuring access to anti-TB medicines, and particularly those to treat drug resistant TB, are manifold.

The scale of Multi-Drug Resistant (MDR)-TB is already growing in many countries, and most recently, the epidemic of extensively drug-resistant TB (XDR-TB) has emerged. Addressing drug-resistant TB requires a massive increase of resources to treat patients with second-line drugs and to improve programme performance to prevent further development of resistance.

An essential component of successful treatment of TB and the prevention of MDR-TB is the uninterrupted supply of quality assured medicines. The causes of MDR-TB include erratic medicine intake (particularly interruptions of treatment) and treatment with a single TB medicine. First-line FDCs were developed primarily as a tool to mitigate the emergence of resistance. While many countries have adopted FDCs during the last decade, FDCs are still only used by approximately half of those reporting to the WHO: out of 136 countries that reported to the WHO in 2007, FDCs of two, three or four medicines were used by approximately 50% of them. Globally, however, only about 15% of new patients receive FDCs. If countries are to rise to the challenge of treating all those in need, they will need access to sufficient supplies of affordable FDCs produced to stringent standards.

The worldwide supply of quality assured second-line medicines to treat MDR-TB is even more significantly constrained than that of first-line FDCs. At present, the volumes of these medicines produced under stringent oversight are woefully insufficient to treat the increasing numbers of patients being enrolled for care throughout the world. As a result, the majority of patients being treated for MDR-TB are receiving medicines of uncertain quality. Compared to the estimated global incidence of ~500,000 MDR-TB patients per year, only 3% are currently enrolled in programmes approved by the WHO's Green Light Committee (GLC) and receive medicines that are quality assured.

The fact that new TB diagnostic tools such as commercial liquid culture systems, as well as molecular line probe assays for rapid detection of MDR-TB, have been recently endorsed by the WHO and are now being procured by GDF for high burden TB countries (under the umbrella of Stop TB's Global Laboratory Initiative) further compounds the access challenge: as scaled up and improved diagnosis generates scores of new patients, the availability of sufficient treatments is an ethical imperative.

In the face of these challenges, GDF's top priority over the next few years will be to work with its partners, particularly financing mechanisms such as the Global Fund and UNITAID that have the financial wherewithal to positively impact TB medicine market dynamics, to further expand the number of sources of quality assured anti-TB medicines. This is already under way through a tiered system of quality assurance involving the WHO's Prequalification Programme and stringent National Medicines Regulatory Agencies (NMRAs).

GDF and such partners will also need to establish stable and affordable benchmark prices, particularly for quality assured second-line medicines, which still remain exorbitantly priced even after price reductions of 60-90% achieved through the GLC mechanism over the last decade.

Lastly, improving the capacity of NMRAs in low/lower income countries to ensure the production of anti-TB medicines of assured quality is a necessity, and the only path towards sustainable production of TB medicines that are safe and efficacious. GDF, in collaboration with the WHO, stringent NMRAs and interested donors, could broker technical support to high burden TB countries to strengthen the capacity of their NMRAs and, where appropriate, the competence of their manufacturers.

The creation of additional capacity to manufacture existing anti-TB medicines to stringent standards through the above interventions is critical to ensuring sufficient and secure supplies until new, more effective classes of anti-TB medicines are developed, also under the auspices of the global plan, but it

is a prospect that is still a few years away. The recently endorsed WHO World Health Assembly Resolution on M/XDR-TB and the commitments to which it binds member states is expected to provide a strong impetus to such initiatives.

Conclusion

GDF's record has laid a solid foundation upon which further progress can be built in spite of the myriad challenges that continue to confront access to anti-TB medicines in the world's poorest countries. When the GDF's blueprint was written in 2000, it projected that the facility would provide drugs to approximately 10 million patients during its first five years, serve as a model for improving the management of other diseases, strengthen health systems and contribute to sustaining improvements made in the global capacity to control TB. It has made significant progress towards realising these goals, but much work remains to be done. With an innovative global plan, a well functioning and enabling Stop TB Partnership, and strong financing partners such as the Global Fund and UNITAID, the landscape is ripe with the opportunity and the tools to make even greater gains in the fight to ensure that all TB patients are afforded their inalienable right to effective treatment.