South Centre Statement on World TB Day

Countries need to step up the response to tuberculosis and take all possible measures to expand access to treatment.

As the world continues the struggle to end the global COVID-19 pandemic, this World TB Day marks a sombre occasion to recall 1.8 billion people across the world are infected with TB. Despite the fact that TB is curable and preventable, it remains the leading cause of death from an infectious agent. Growing resistance to existing TB drugs has led to increasing cases of drug resistant TB making the disease more deadly and difficult to treat. Most of the infected patients are from the countries of the global South, with eight countries accounting for two thirds of the total TB cases, with India leading the count, followed by Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa.

The COVID-19 pandemic has aggravated the gap in access to treatment for TB substantially for many patients; there is a need to reboot the national and global effort to end the disease.[1] Access to affordable treatments for drug resistant TB remains a major challenge for the high burden TB countries from the global South.

It is hope inspiring for patients that new drugs have been developed in recent years for the treatment of drug resistant TB. These drugs - bedaquiline, delamanid and pretomanid - used as part of treatment regimens offer patients a better chance of being cured without debilitating side effects. Bedaquiline and delamanid are included in the WHO Model List of Essential Medicines for the treatment of TB.[2] The WHO guidelines for the treatment of drug resistant TB recommend the use of bedaquiline and delamanid,[3] therefore encouraging countries to update the treatment regimens to include these newer TB drugs.

However, many high TB burden countries have been unable to scale up access to these drugs. High prices and lack of generic competition are significant barriers. Initiatives

[1] World Health Organization (WHO), "COVID-19 highlights urgent need to reboot global effort to end tuberculosis", News Release, 22 March 2021. Available from https://www.who.int/news/item/22-03-2021-covid-19-highlights-urgent-need-to-reboot-global-effort-to-end-tuberculosis.
[2] See WHO, Model List of Essential Medicines. Available from https://list.essentialmeds.org/.
[3] See WHO, *WHO Consolidated Guidelines on Drug Resistant Tuberculosis Treatment* (Geneva, World Health Organization, 2019). Available from https://www.who.int/tb/publications/2019/consolidated-guidelines-drug-resistant-TB-treatment/en/.

such as the Stop TB Partnership's Global Drug Facility, and the interventions by the Global Fund for AIDS, TB and Malaria and Unitaid, provide some support for procurement of TB drugs. However, countries that are not eligible under these programmes have to rely either on voluntary donations or procure the drug at market prices from the limited producers available. Moreover, the reduced prices currently available through international access programmes could benefit from further reductions with the entry of generics, which would allow countries to expand treatment. For example, bedaquiline is available at a price of $340 for a six month course through the Global Drug Facility, while it has been estimated that the price of generic bedaquiline could be as low as $7-17 per patient per month[4]. The same study estimates that the price of generic delamanid could be about $4-18 per patient per month, and the price of generic pretomanid could be about $10-34 per patient per month.[5] Thus, availability of the generic drugs for the treatment of drug resistant TB could allow countries to speed up the roll out of shorter, effective treatments by significantly reducing the costs.

The main impediment to broaden availability of generics of the newer TB-drugs is the fact that the pharmaceutical companies hold various patents for the drugs in many high burden TB countries, meaning that production and commercialization can be carried out only by the patent holders or another company that is licensed by them under agreed terms and conditions. Hence, a generic version of the drug can be produced during the term of the patent only on the basis of a voluntary license from the patent holder or if governments exercise their right to issue a compulsory license, in view of the public health need for scaled up and affordable access to those drugs. The patent holder is to be compensated and can continue to produce and sell in the territory. Several patents have been granted on bedaquiline in many of the high burden TB countries such as India, China, Indonesia, Pakistan, the Philippines and South Africa. In some of these countries 'secondary' patents have been granted or filed on salt forms, dosage forms or use for treatment of MDR-TB in combination with other drugs such as pretomanid. Similarly, patents have been filed and granted on delamanid in these countries.[6] Application of rigorous patentability requirements is a mechanism, consistent with the WTO TRIPS Agreement, that could be used to limit such secondary patents on these essential TB drugs.[7]

So far, the companies that hold the patent rights over these drugs have refused to grant voluntary licenses to generic manufacturers on terms that can be beneficial for access, including non-exclusive voluntary licenses through the Medicines Patent Pool. In view of

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[4] See Dzintars Gotham, *et al.,* "Estimated generic prices for novel treatments for drug-resistant tuberculosis", *Journal of Antimicrobial Chemotherapy*, vol.72 (Issue 4), 2017, pp.1243-52. Available from https://academic.oup.com/jac/article/72/4/1243/2884272?login=true#63591574.

[5] ibid.

[6] See Medicines Patent Pool, MedsPaL: The Medicines Patents and Licenses Database. Available from https://www.medspal.org/?page=1.

[7] Some developing countries and international organizations have developed guidelines that ensure a robust examination of pharmaceutical patent applications. See, e.g., United Nations Development Programme (UNDP), *Guidelines for the Examination of Patent Applications Relating to Pharmaceuticals*, 16 June 2016. Available from https://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html.

the public health emergency that exists in the high burden countries, their governments have the full freedom under the WTO TRIPS Agreement, as clarified by the 2005 WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, to authorize the government use for non-commercial purposes or issue compulsory licenses to allow the generic manufacturing of these drugs to expand access to treatments. There is capacity in many developing countries, such as India, to produce affordable generic versions of the drugs necessary for treatment of drug resistant TB, under such authorization. Thus, for example, the government could "…authorize a relevant department or ministry to exploit by itself or through a contractor, such as a public corporation or a private generic pharmaceutical company, to manufacture and supply the patented drug without the consent of the patent holder."[8]

On the occasion of World TB day, the South Centre encourages developing countries to apply robust patentability criteria, and to authorize production of essential TB drugs for government use or compulsory licenses if these are patent-protected in their territories to scale up treatment for and stall spread of drug-resistant TB, in line with the Sustainable Development Goal of ending the TB epidemic by 2030.

[8] Carlos M. Correa, *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents,* Research Paper 107 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/04/RP-107.pdf.