

To: Jennifer Power
Country Manager
Pfizer South Africa
85 Bute Rd
Sandton, 2196
South Africa

14 December 2015

Open Letter to Pfizer Regarding Pricing and Availability of Linezolid in South Africa

Dear Ms. Jennifer Power:

We are writing to urge Pfizer to immediately reduce the price of linezolid in South Africa, and instead offer linezolid at a price in line with that offered through the Global Drug Facility, in South Africa and other high-burden tuberculosis (TB) countries in the region. We also request that Pfizer clarify its supply capabilities and plans for providing linezolid 100mg/5ml suspension, for use in children. Recent shortages of this formulation have been reported in the Western Cape provincial depot, and globally.

The growing drug-resistant TB (DR-TB) epidemic remains one of the biggest threats to the health of the South African citizenry.¹ Linezolid is recommended in the World Health Organisation² and the South African National Department of Health (NDOH) policy guidelines for treating DR-TB.³

In 2015, the NDOH was unable to secure linezolid at an affordable price through its state tendering process for the public sector.⁴ The NDOH requested bids to supply 114,500 units of 10x600mg tablet packs of linezolid over two years⁵—enough supply to provide a six-month course of linezolid to a targeted 3,000 people with DR-TB per year.^{6,7} Failure to secure a bidder for the tender suggests your company—one of only two registered to supply linezolid in South Africa—has not offered a bid to supply it at an affordable price, or at all.

South Africa and Swaziland benefit from Global Fund support but purchase medicines independently of its supply channel, the Global Drug Facility (GDF). As high-burden TB countries, there is a public health imperative for South Africa and Swaziland to receive linezolid prices on par with the GDF, which currently stands at US\$5.35-5.48 per 600 mg tablet⁸ (~R76)⁹. By contrast, the price offered by your company for a single 600mg tablet of linezolid in the South African private sector is a restrictively high R875 (US\$62).¹⁰ Health care facilities wishing to use linezolid for patients with DR-TB in the public sector must purchase it directly from registered suppliers. The prices offered by Pfizer for public sector patients are also significantly higher than GDF prices, at R214 (~US\$15.50) per tablet.

¹<http://www.statssa.gov.za/publications/P03093/P030932013.pdf>

²http://apps.who.int/iris/bitstream/10665/44597/1/9789241501583_eng.pdf

³<http://www.hst.org.za/sites/default/files/TBpolicy.pdf>

⁴<http://www.health.gov.za/tender/docs/contracts/HP022015AICC.pdf>

⁵<http://www.health.gov.za/tender/docs/tenders/HP022015AI01Bid.pdf>

⁶ This calculation is based on a DR-TB patient taking one 600mg tablet per day for a total of six months (182 tablets in total). As linezolid is indicated for infections other than TB, it is assumed the excess number of tablets (beyond what is required for 3,000 DR-TB patients per year initiated on a six-month regimen) would be used for treating patients with these conditions.

⁷<http://www.health-e.org.za/2015/06/11/more-than-r130-million-slated-for-new-tb-drugs/>

⁸<http://www.stoptb.org/gdf/drugsupply/pc3.asp?PID=818>

⁹ All exchange rates as of October 29, 2015 on <http://www.xe.com/currencyconverter/>

¹⁰ Prices as of October 29, 2015 at <http://mpr.code4sa.org/#search:linezolid>

The market for linezolid in South Africa and the region is growing rapidly as countries scale up access to DR-TB treatment. More than 18,000 patients are diagnosed with DR-TB in South Africa each year. Many of these patients could benefit from the inclusion of linezolid in their DR-TB regimen, and from using linezolid for longer than six months. Countries like Swaziland rely on South African MCC approvals and closely follow South African practices for determining when to introduce new drugs such as linezolid, adding additional market potential. Companies like yours should reach greater economies of scale, and be able to offer their products at low prices to all high-burden TB countries, regardless of the size of an individual country's demand.

An additional challenge with linezolid arose in late November 2015, when the Stop Stock Outs project—a civil society consortium monitoring stock outs in South Africa—received reports that the Western Cape provincial depot had run out of pediatric linezolid (100mg/5ml suspension, produced by Pfizer). This shortage left 20 children on DR-TB treatment without access to their standard formulation. These children are now being treated with crushed adult tablets of linezolid, but this practice could lead to sub-optimal dosing and wastage of this expensive formulation. At the same time, the GDF has confirmed a global stock out of the 100mg/5ml suspension. We urge Pfizer to establish emergency measures to ensure rapid additional production and delivery of linezolid 100mg/5ml suspension for children, in order to alleviate shortages faced by South Africa and other countries. Pfizer should also outline a plan for sustainable supply of this formulation in the future.

Linezolid is one of the key companion drugs to the new DR-TB drugs that are being scaled up in South Africa and Swaziland. Yet linezolid remains one of the most expensive drugs within a DR-TB regimen, and a daily dose costs approximately double that of bedaquiline in South Africa. Affordable linezolid prices and consistent supply of pediatric linezolid formulations in South Africa could facilitate greater access to these more robust DR-TB regimens and contribute to reducing DR-TB morbidity and mortality. Greater access to treatment is a crucial component in curbing the spread of the disease and limiting the development of further drug resistance. We urge Pfizer to immediately lower linezolid prices and offer formulations of linezolid on a consistent and sustainable basis to South Africa and other countries in the region. Clinicians and patients can no longer wait for more affordable linezolid for DR-TB regimens.

We request your rapid response, and an urgent meeting to clarify the future availability of pediatric linezolid supply to South Africa. Please direct all correspondence regarding this issue to Julia Hill at msfocb-capetown-deputyhom@brussels.msf.org.

Sincerely,

