

Mr. Marty Ross
Vice President of Sales
Amneal Pharmaceuticals
Account Management, Sales Operations & Customer Response
118 Beaver Trail
Glasgow, KY 42141
United States

17 December 2015

Open Letter to Amneal Regarding Registration and Pricing of Linezolid in South Africa

Dear Mr. Marty Ross:

We are writing to urge your company to file for registration of linezolid 600mg tablets and other linezolid formulations with the Medicines Control Council (MCC) of South Africa, and subsequently 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, such as Swaziland.

We understand that Amneal linezolid 600mg tablets have received tentative approval from the U.S. Food and Drug Administration. The signatories to this letter support the registration of multiple quality-assured sources of linezolid in South Africa, in order to address high prices that currently prevent linezolid from being offered to all patients with drug-resistant tuberculosis (DR-TB) who could benefit from its use. Additionally, over 100 South African clinicians and organisations have called on South Africa's MCC to prioritise rapid registration of quality-assured generic linezolid.¹

The growing drug-resistant TB (DR-TB) epidemic remains one of the biggest threats to the health of the South African citizenry.² Linezolid is recommended in the World Health Organisation³ and South African National Department of Health (NDOH) policy guidelines for treating DR-TB.⁴ As South Africa and other countries in the region, such as Swaziland, scale up access to DR-TB treatment, the demand for linezolid is growing rapidly, and there is increased potential for manufacturers to reach economies of scale and offer lower prices. Yet the NDOH, despite having one of the largest known demands for linezolid globally, has been unable to secure linezolid at an affordable price through its state tendering process for the public sector.^{5,6}

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 prices on par with the GDF, which currently stands at US\$5.35-5.48 per 600 mg tablet⁷ (~R76).⁸ Yet, at present, linezolid costs a minimum of R655 (US\$47) per 600mg tablet in the private sector, and is only available to public sector patients when health care facilities negotiate prices directly from registered suppliers. Affordable supplies of linezolid for the national public sector are urgently needed in South Africa and other countries in the region.

¹ <http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201411/MCC%20linezolid%20letter.pdf>

² <http://www.statssa.gov.za/publications/P03093/P030932013.pdf>

³ http://apps.who.int/iris/bitstream/10665/44597/1/9789241501583_eng.pdf

⁴ <http://www.hst.org.za/sites/default/files/TBpolicy.pdf>

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

⁶ <http://www.health.gov.za/tender/docs/contracts/HP022015AICC.pdf>

⁷ <http://www.stoptb.org/gdf/drugsupply/pc3.asp?PID=818>

⁸ Exchange rates as of October 29, 2015 on <http://www.xe.com/currencyconverter/>

In 2015, the NDOH requested bids to supply 114,500 units of 10x600mg tablet packs of linezolid over two years⁹—enough supply to provide a six-month course of linezolid to a targeted 3,000 people with DR-TB per year.^{10,11} The market for linezolid in the region is potentially much larger than the NDOH request, as 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 without extra regulatory efforts.

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. Amneal linezolid registration and entry on the South African market at an affordable price could facilitate greater access to 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 strongly urge Amneal to submit linezolid for registration to the South African MCC and subsequently provide linezolid to countries in the region at a price on par with the lowest global prices of quality-assured products. Clinicians and patients can no longer wait for more affordable linezolid for DR-TB regimens.

We request your rapid response by the end of 2015, and would welcome a meeting to discuss these issues further. Please direct all correspondence regarding this issue to Erica Lessem via erica.lessem@treatmentactiongroup.org.

Sincerely,



⁹<http://www.health.gov.za/tender/docs/tenders/HP022015AI01Bid.pdf>

¹⁰ 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.

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