

To: Kevin Moodaley  
Head of Operations  
Hetero Drugs SA  
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Centurion 0157  
South Africa

To: John Fagan  
General Manager  
Sanofi SA  
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Grand Central Extension 1  
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South Africa

**14 December 2015**

### **Open Letter to Hetero and Sanofi Regarding Pricing of Linezolid in South Africa**

Dear Kevin Moodaley and John Fagan:

We are writing to urge Hetero and Sanofi to immediately reduce the price of linezolid 600mg tablets in South Africa, and instead offer linezolid at a price in line with that offered by Hetero through the Global Drug Facility, in South Africa and other high-burden tuberculosis (TB) countries in the region.

The growing drug-resistant TB (DR-TB) epidemic remains one of the biggest threats to the health of the South African citizenry.<sup>1</sup> Linezolid is recommended in the World Health Organisation<sup>2</sup> and South African National Department of Health (NDOH) policy guidelines for treating DR-TB.<sup>3</sup>

In 2015, the NDOH was unable to secure linezolid at an affordable price through its state tendering process for the public sector.<sup>4</sup> The NDOH requested bids to supply 114,500 units of 10x600mg tablet packs of linezolid over two years<sup>5</sup>—enough supply to provide a six-month course of linezolid to a targeted 3,000 people with DR-TB per year.<sup>6,7</sup> Failure to secure a bidder for the tender suggests the Hetero product—one of only two registered linezolid products in South Africa, marketed by Sanofi—has not been offered at an affordable price.

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 price Hetero provides to the GDF, which currently stands at US\$5.35-5.48 per 600 mg tablet<sup>8</sup> (~R76).<sup>9</sup> By contrast, the price offered for a single 600mg tablet of Hetero/Sanofi linezolid in the South African private sector is a restrictively high R655 (US\$47).<sup>10</sup> 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 quoted by Sanofi for public sector

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

<sup>2</sup>[http://apps.who.int/iris/bitstream/10665/44597/1/9789241501583\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44597/1/9789241501583_eng.pdf)

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

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

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

<sup>6</sup> 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.

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

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

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

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

patients are also significantly higher than GDF prices, ranging from R159 (~US\$11.50) to R590 (~US\$42.50) per tablet.<sup>11</sup>

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.

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 in South Africa will 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 Hetero and Sanofi to immediately lower linezolid prices in South Africa and the region. Clinicians and patients can no longer wait for more affordable linezolid for DR-TB regimens.

We request your rapid response, and would welcome a meeting to discuss these issues further. Please direct all correspondence regarding this issue to Julia Hill at [msfocb-capetown-deputyhom@brussels.msf.org](mailto:msfocb-capetown-deputyhom@brussels.msf.org).

Sincerely,



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<sup>11</sup> Sanofi quoted the Western Cape Provincial Department of Health a price of approximately R159 per tablet in June 2015. When Doctors Without Borders (MSF) in South Africa sought to access linezolid from Sanofi in South Africa, in order to fill a short-term supply gap while it waited for an order from its European supply centers, the price quoted was R590 per tablet.