To: Ms. Mandisa Hela
The Registrar of Medicines
Medicines Control Council
Private Bag X828
Pretoria 0001
Per email: helam@health.gov.za
Per fax: +27 12 395 9201

30 October 2014

Dear Ms. Hela:

We, the undersigned clinicians, health care providers, DR-TB patients, and civil society organisations, commend the Medicines Control Council (MCC) on its June 26th, 2014 decision, granting Doctors Without Borders (MSF) authorisation to use a generic linezolid product in treatment regimens for selected patients with drug-resistant tuberculosis (DR-TB) in Khayelitsha, Western Cape[1]. This is an important first step toward expanding access to linezolid for DR-TB patients in South Africa. However**, we urge the MCC to immediately register the same generic linezolid product currently under a fast-track review, in order to ensure linezolid is available for all DR-TB patients in need across the country.**

The MSF application under section 21 of the *Medicines and Related Substances Act 101 of 1965* ("the Act") was based on the unaffordability of the brand name product, Zyvoxid. Prior to the MCC authorisation, MSF purchased Zyvoxid at the exorbitant private sector price of over R700 per 600mg tablet. The cost of this single drug consumed over 10% of the annual MSF operational budget for HIV and TB programmes in Khayelitsha, limiting the number of patients to whom linezolid could be offered. The generic product from manufacturer, Hetero, is purchased by MSF at less than R80 per tablet—a price reduction of over 88%--and provided in terms of the section 21 authorisation from the MCC.

Other clinicians in South Africa are also struggling to offer linezolid to all patients who might benefit from the drug's use, due to the unaffordability of Zyvoxid. Patients who must access Zyvoxid through the private sector are finding it is not covered by their medical aid due to the high cost, and they cannot afford it on an out-of-pocket basis.[2]

The MCC granted MSF section 21 authorisation after confirming the Hetero product's approval by the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA)—a stringent drug regulatory authority and fellow member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The same product dossier was submitted to the MCC for full registration in South Africa on the 29 April 2013, and granted fast-track approval status on 6 June 2013. Hetero made a full submission in this regard to the MCC on the 12 June 2013, after which the MCC should have supplied a decision within nine months, in line with Regulation 5 of the General Regulations made in terms of the Act. Over 16 months have now passed, with no decision concerning the application for registration reaching Hetero, to our knowledge.

[1] https://www.msf.org.za/msf-publications/more-msf-patients-with-dr-tb-gain-access-to-dramatically-cheaper-version-life
[2] http://www.health-e.org.za/2014/10/03/xdr-tb-patients-smuggle-pills-treatment-priced-reach/

It is unclear to the parties signing this letter why the MCC deems the generic product of sufficient quality for MSF to use, but has not yet fully registered the drug. Full registration of one or more quality generics would allow the National Department of Health to open a more competitive tender and obtain a more affordable linezolid product to address the huge public health impacts of the TB epidemic. It would allow clinicians across South Africa to have fewer concerns for cost when prescribing linezolid to DR-TB patients in need, in line with national guidelines. **Most importantly, the availability of generic linezolid would help save DR-TB patients' lives.**

Clinicians across South Africa consistently struggle to offer adequate treatment regimens for patients with DR-TB. The current treatment course for DR-TB is at least two years, and patients sometimes take more than 20 pills per day and suffer painful injections for the first six months of treatment. The only medicines available can have devastating side effects—including deafness and psychosis—and the cost of a treatment regimen is significantly higher than that for standard, drug-sensitive TB.

World Health Organisation[3] and national[4] guidelines in South Africa recommend linezolid as a third-line drug for DR-TB treatment, when cost permits. These guidelines highlight the importance of linezolid in designing treatment regimens strong enough to combat extensively drug-resistant TB (XDR-TB) and pre-XDR TB. The drug is also one of few available options for patients who do not tolerate standard DR-TB therapies. We estimate that every year, at least 1,000 patients diagnosed with DR-TB in South Africa would be eligible candidates for a linezolid-containing regimen, if cost were not a prohibitive factor. For DR-TB patients, access to an adequate regimen means the difference between life and death.

Earlier this year, the sinister intentions of the multinational pharmaceutical industry to block access to generic medicines were made glaringly obvious. Documents leaked to the media revealed a US$600,000 plot by 25 multinational pharmaceutical companies to protect profit margins at the expense of public health, by delaying reform of South Africa's patent laws through a covert campaign.[5] In order to counter the corporate interests exposed during "Pharmagate," strong leadership that promotes access to medicines and advances the constitutional right to access healthcare services in South Africa is required from state bodies like the MCC. Registration of generic linezolid would be a clear step forward in the right direction, and help address a disease and public health emergency that is the leading cause of death in South Africa. Further delays in registering a quality-approved generic are unconscionable.

We urge the MCC to register generic Hetero linezolid as a matter of urgency, or to provide urgent clarification on why registration is being delayed. We look forward to your prompt response.

Sincerely,

Current and Former DR-TB Patients Who Have Benefitted from the Inclusion of Linezolid in their Treatment Regimens

Phumeza Tisile—Khayelitsha, Western Cape
Andaleeb Rinquest—Cape Town, Western Cape
Morgan Scholtz—Kleinkranz, Western Cape
Mary McNally—Cape Town, Western Cape

[3] http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf?ua=1
[4] http://www.hst.org.za/sites/default/files/TBpolicy.pdf
[5] http://keionline.org/node/1908

Organisations:

TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

TAG
Treatment Action Group

EQUAL EDUCATION

DESMOND TUTU TB CENTRE • SENTRUM • IZIKO
UNIVERSITY I STELLENBOSCH I UNIVERSITEIT

TAC
TREATMENT ACTION CAMPAIGN

St.Lukes Hospice* (NPC)
Accredited to the Hospice Palliative Care Association

ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

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