To Date

Name of the minister

Honorable Minister of Health, Ministry of Health,

Government of (Your Country)

Cc

The Prime Minister’s Office, Government of (Your Country)

Minister of Finance, Ministry of Finance, Government of (Your Country)

TB Programme Head, (Your Country)

Other Senior Government Official stakeholder in TB Programme in Your Country

**Subject: Injection-free MDR TB treatment**

Dear Hon. Minister (Name)

We write to you as members of the TB affected community and Civil Society in (Your Country) and globally. We commend the Government of (Your Country) for the recent advances in addressing Tuberculosis in (Your Country) and the bold steps taken so far to end TB.

However Tuberculosis continues to be a major health emergency in (Your Country) According to WHO Global TB Report 2017, our country is the (Global rank) burden TB country in the world and had an estimated **(your country data)** people fall ill with TB in 2016, with **(your country data)** deaths the same year. To make matters worse, **(your country data)** new cases of TB in (Your Country) were drug-resistant.

One of the biggest challenges with TB is diagnosis of people affected by TB and ensuring that they are put on the right treatment. According to the Global TB Report 2017, only one in five persons with MDR-TB was started on treatment. Treatment success remains low at a bleak 54% globally.

Last week, the global medical community woke up to the welcoming news that South Africa had become the first country to recommend an injection-free, bedaquiline-based regimen for ALL patients with rifampicin-resistant tuberculosis. We sincerely hope that (Your Country) follows suit immediately.

We request the Health Ministry to take necessary steps to ensure that bedaquiline replaces the injectable medicines that currently form part of (Your Country) standard treatment regimen for rifampicin-resistant tuberculosis (RR-TB). Bedaquiline should be used in children aged 12 and older as they metabolize the drug similarly to adults. As paediatric studies of bedaquiline are ongoing in children under 12, we request the Health Ministry to ensure an appropriate injectable-free regimen for children under 12, who are particularly vulnerable to hearing loss. For children under 12 years old with less severe disease, the Health Ministry should drop the injectable without replacement in line with 2016 World Health Organization recommendations for children[[1]](#footnote-1). For children under 12 years with more severe forms of disease, the Health Ministry should replace the injectable with delamanid—which has been shown to be very safe, and its paediatric use is recommended by the World Health Organization[[2]](#footnote-2).

The injectables are associated with a number of serious side effects, including causing permanent damage such as irreversible hearing loss in as many as 50 percent of patients[[3]](#footnote-3), and their efficacy against drug-resistant TB has not been validated in a clinical trial. Streptomycin is not recommended by the Word Health Organization as part of standard treatment of rifampicin-resistant TB , and its use in (Your Country) especially under the Category II regimen should be stopped immediately in accordance with World Health Organization guidance[[4]](#footnote-4).

Bedaquiline, on the other hand, has had several clinical trials and has already been approved by stringent regulatory authorities since 2012 and in (Your Country) since (Year). It has been seen with recent studies that regimens containing bedaquiline were associated with a 41% increase in treatment success and a 3-fold reduction in mortality[[5]](#footnote-5).

Quoting from a study[[6]](#footnote-6) that was published last year, the authors conclude: "There is limited evidence of the efficacy of IAs [injectable agents], clear evidence of the risks of these drugs, and that persons living with MDR-TB should be informed about these risks and provided with access to alternative therapeutic options" namely, bedaquiline and delamanid.

Patients with MDR-TB are suffering from painful injectables and permanent hearing loss from injectables, when there are more effective evidence-based treatment options available like bedaquiline, as well as new TB drug delamanid.

Additionally, we request that the Health Ministry ensure that people with pre-extensively drug-resistant TB (pre-XDR) and XDR-TB, or intolerance to drugs that render their TB effectively pre-XDR or XDR, have access to both bedaquiline and delamanid. There will be many patients who will need both, particularly in (Your Country), and evidence so far on the co-administration of the two drugs shows that it is promising for patients with limited treatment options.[[7]](#footnote-7)

We hope that the (Your Country) Government takes the necessary action keeping in mind that every person who is affected by TB has the right to access drugs that will cure them and not leave them with permanent disability.

We look forward to your response by the end of this month and are committed to supporting the ministry and the TB programme in providing the highest quaity care and ending TB in (Your Country).

For further information, kindly contact (Name), (Organisation Name), on (Contact No.), or email at (email address)

Respectfully submitted by,

Affected Communities and Civil Society

1. http://apps.who.int/iris/bitstream/handle/10665/250125/9789241549639-eng.pdf?sequence=1 [↑](#footnote-ref-1)
2. http://www.who.int/tb/publications/Delamanid\_interim\_policy/en/ [↑](#footnote-ref-2)
3. http://www.tbonline.info/media/uploads/documents/who\_must\_recommend\_bedaquiline\_for\_all\_patients\_with\_mdr\_tb.pdf [↑](#footnote-ref-3)
4. http://apps.who.int/iris/bitstream/handle/10665/255052/9789241550000-eng.pdf?sequence=1 [↑](#footnote-ref-4)
5. https://www.ghdonline.org/drtb/discussion/global-tb-cab-welcomes-introduction-of-safer-drug-/ [↑](#footnote-ref-5)
6. http://www.ingentaconnect.com/content/iuatld/ijtld/2017/00000021/00000011/art00006;jsessionid=199yqjqho10jr.x-ic-live-02 [↑](#footnote-ref-6)
7. <http://erj.ersjournals.com/content/52/1/1800934.long> [↑](#footnote-ref-7)