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Department:  
Health  
REPUBLIC OF SOUTH AFRICA



## MEDIA STATEMENT

To: Editors & Health Journalists  
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### **New Bedaquiline data shows reduction in TB mortality cases**

**Pretoria:** The Department of Health has released new data on reduction in TB mortality cases from drug resistant Tuberculosis (DR - TB) in South Africa through use of the latest medicine, called Bedaquiline.

South Africa has a large number of people with drug resistant tuberculosis, many of whom were diagnosed since the expanded use of the latest diagnostic technology – GeneXpert in 2011. Treating patients with drug resistant tuberculosis has been difficult with old medicines used which had many negative side effects and over long periods – often up to 24 months.

However, a new medicine for the treatment of drug resistant tuberculosis, Bedaquiline, became available in 2013 and the National Department of Health was granted permission by the Medicine Control Council(MCC) to provide Bedaquiline to drug resistant TB patients who had limited treatment options, through the Bedaquiline Clinical Access Program (BCAP).

Two hundred patients who were either pre-XDR TB or had XDR TB, received the medicine under controlled conditions. Of the 200 patients between March 2013 and March 2015, three quarters (146/200) had a favourable outcome (cure and treatment completion). Twenty - five patients (12.5%) died, which was much lower than the 50% for patients not receiving Bedaquiline. It was also found that patients on a Bedaquiline regimen also reported far fewer adverse events.

According to the Department, following registration of Bedaquiline by the Medicine Control Council (MCC) now called South African Health Products Regulatory Authority (SAHPRA), the National TB Programme (NTP) made the medication available more widely. About 15,000 Rifampicin Resistant Tuberculosis (RR-TB) patients have either received or are currently receiving Bedaquiline under programmatic conditions, which is approximately two-thirds of the global uptake of Bedaquiline. Rifampicin Resistant Tuberculosis is a severe form of TB where the patients have germs that are resistant to Rifampicin, which is the strongest TB medicine.

A retrospective cohort analysis of records of all Rifampicin Resistant Tuberculosis patients receiving treatment regimens inclusive of Bedaquiline were associated with a 41% increase in treatment success and a 3-fold reduction in mortality compared with those that did not get the medication. The Department has taken a decision to now make Bedaquiline available to all eligible Rifampicin Resistant Tuberculosis patients, that is, not only the extensively drug resistant TB patients or those with limited treatment options as done previously.

This means that for the first time, an injection free regimen will be recommended for all patients with Rifampicin Resistant Tuberculosis patients in South Africa. Additionally, patients with MDR-TB will now also receive Bedaquiline as part of more patient friendly short regimen which is expected to improve adherence and ensure success.

***For enquiries and more information, please contact***

<b>Media Enquiries:</b> Mr Foster Mohale Director: Media Relations National Department of Health Mobile: 0724323792 Foster.mohale@health.gov.za	<b>Technical Enquiries:</b> Dr Norbert Ndjeka, Director: DR-TB National Department of Health Mobile: 082 451 8142 Email: Norbert.Ndjeka@health.gov.za
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