



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL

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Global Tuberculosis Community Advisory Board (TB CAB)

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Attention: Erica Lessem and Nathan Geffen

**RE: OPEN LETTER TO THE MEDICINES CONTROL COUNCIL AND
MINISTRY OF HEALTH ON URGENT NEED FOR COMPASSIONATE USE OF
BEDAQUILINE (TMC 207) FOR XDR-TB AND PRE-XDR-TB IN SOUTH
AFRICA**

Your communication dated 11 April 2012 refers.

Kindly be advised that the MCC has been engaged in discussions with the TB Chief Directorate of the National Department of Health since November 2011, at which time the TB Chief Directorate requested expanded access to TMC 207, i.e., beyond the trial participants.

Several safety related matters were raised during these discussions, amongst others that of QTc prolongation and the possible interactions with other medicines, including ARVs. The TB Chief Directorate subsequently requested to postpone the discussions until a later date. The TB Chief Directorate then requested to have an oral presentation at the MCC meeting scheduled for Friday 20 April 2012, which was granted. During discussion following this presentation on 20 April, the TB Chief Directorate representatives responded to some of the questions that were raised by Council members. This included that expanded access would be implemented under the control of the TB Chief Directorate and would be closely monitored.

The MCC resolved that:

1. Although the motivation for the use of TMC-207 in XDR and pre-XDR TB patients is compelling, current available data is limited and premature.

2. Providing access to patients in this context would best be achieved through a formal clinical trial, such as an open-label design.
3. The National Department of Health be requested to submit a clinical trial protocol for review by the MCC and relevant Ethics Committees. Such a review will be expedited.
4. The National Department of Health has been advised of this resolution.

Yours faithfully



REGISTRAR OF MEDICINES

DATE: 26/4/2012