



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr Erica Lessem, MPH
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London, 6 July 2012
EMA/458689/2012

Dear Dr. Lessem and Members of the Global Tuberculosis Community Advisory Board

Reply Letter to Open Letter Re: Conducting drug-drug interaction studies for bedaquiline (TMC207) and delamanid (OPC6783)

We thank you for your letter dated 24th May in relation to the envisaged need of conducting drug-drug interaction studies between the two new investigational TB drugs bedaquiline and delamanid.

We appreciate your concerns and your suggestion has been transmitted to the EMA main Scientific Committee, the CHMP, for consideration in due course.

Thanks also for the continuous interest in the activities of the Agency and we look forward to further fruitful discussions in the future.

Yours sincerely,

Guido Rasi
Executive Director

Cc: Mr John Dalli, European Commissioner for Health and Consumer Policy
Prof Hans-Georg Eichler, Senior Medical Officer, EMA
Mr Patrick Le Courtois, Head of Unit Human Medicines Development and Evaluation, EMA
Dr Marco Cavaleri, Section Head Anti-Infectives, Vaccines, EMA

