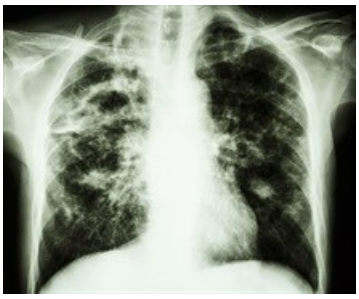
Approval by MCC of new TB drug welcomed

South Africa has the second highest rate of new tuberculosis (TB) cases in the world and the highest rate of drug-resistant TB cases in Africa. TB remains a major public health problem in South Africa because 73% of TB patients are also living with HIV.



Approximately 3,000 South African patients who suffer from multidrug-resistant tuberculosis (MDR-TB) will now be able to receive SIRTURO (bedaquiline) in the next year, following approval by South Africa's Medicines Control Council (MCC). Janssen Pharmaceutica, part of Johnson & Johnson, developed the medicine. The product will be made available in the public sector for the treatment of MDR-TB in adults 18 years of age, including people living with HIV that are not taking antiretroviral therapy.

"Despite the ease of transmission and high mortality rates, there has been limited progress in the development of treatments for TB in the last several decades," said Dr Francesca Conradie from Right to Care, a non-profit organisation that supports and delivers prevention, care and treatment services for HIV and associated diseases. "The government recognised the need to make this new TB treatment option available for the people who need it most. The impact for my patients and patients around the country will make a difference in their overall health and quality of life."

The decision from the MCC follows the initiation of the drug treatment access programme in March 2013, in which 151 South African patients have been treated to date. A TB culture conversion rate of 80% was recorded for patients who completed six months of treatment with no significant adverse events reported.

"Ten years since the drug was first discovered in our laboratories, we are proud to see this important treatment option brought to the most vulnerable TB patients in South Africa," said Paul Stoffels, Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "We are another major step closer to helping achieve our goal of one day eliminating MDR-TB."

Janssen is collaborating with the South African National TB Directorate to ensure the appropriate use of the drug. The

treatment will be available in the public sector exclusively at designated MDR-TB units. As part of the post-approval commitment to the MCC, Janssen will also be conducting an ongoing medical education programme. In due course, the South African government will be updating its treatment guidelines for the management of TB.