Information note on the use of a new agent, delamanid, for the treatment of multidrug-resistant tuberculosis

On November 22, 2013, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) has recommended the granting of a conditional marketing authorisation for delamanid, a new therapeutic agent, as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. Several national regulatory authorities are in the process of evaluating this compound.

Tuberculosis (TB) is a disease caused by *Mycobacterium tuberculosis* and is one of the world’s deadliest diseases. It is mostly spread from person to person through the air and usually affects the lungs, but it can also affect other parts of the body such as the brain and kidneys. According to WHO, nearly 9 million people around the world became sick with TB in 2012. Multi-drug resistant TB (MDR-TB) occurs when the causative agent, *M. tuberculosis*, becomes resistant to isoniazid and rifampin, the two most effective drugs commonly used to treat TB. MDR-TB results from either infection with organisms which are already drug-resistant or may develop in the course of a patient’s treatment. According to WHO, there were an estimated 450 000 new MDR-TB cases in the world in 2012.

WHO aims to initiate a process of review of available data on the efficacy and safety of this compound, as well as on supplementary data being requested from independent experts. Based on that review, WHO will determine whether to develop interim guidance on the use of this medicine for the treatment of MDR-TB. It is acknowledged that available data on the safety and efficacy of this agent arise from Phase IIb efficacy trials, and that further efficacy and safety data will be needed from rigorously conducted Phase III trial(s). The interim guidance, if and when issued, may thus be modified in future as experience in the use of this drug accrues.

The latest WHO guidance on MDR-TB treatment was issued in 2011 and can be found at: [http://www.who.int/tb/challenges/mdr/programmatic_guidelines_for_mdrtb/en/index.html](http://www.who.int/tb/challenges/mdr/programmatic_guidelines_for_mdrtb/en/index.html). These guidelines present the WHO recommendation for optimal treatment of MDR-TB using combinations of standard anti-TB antibiotics. If a treatment regimen is failing, the recommended practice is to add multiple drugs informed by drug susceptibility testing or by data from drug resistance survey(s). In an effort to maximise the likelihood of successful treatment outcome and prevent acquisition of additional resistance, thus preserving the use of the drugs for future generations of TB sufferers, WHO advises that a single drug deemed to be effective should never be added alone to a regimen to which a patient is not responding.


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