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THE BEDAQUILINE BOOST

Relevant for: Health, Education & Human Resources | Topic: Health & Sanitation and related issues

The “treatment landscape” for patients with multidrug-resistant TB (MDR-TB) is set to be “dramatically transformed” following a recent communication by the World Health Organisation (WHO). Based on assessment of new evidence, the WHO made an important change in the regimen to treat patients with MDR-TB, which is resistant to at least two of the first-line drugs. All injectables are to be replaced with a fully oral regimen to treat MDR-TB patients, and the powerful alternative drug, bedaquiline, has been included in the fully oral regimen.

Injectables to treat MDR-TB can cause serious adverse effects leading to many patients discontinuing treatment midway; the treatment success rate for MDR-TB was only 54% for patients starting treatment in 2014. Replacing injectables with bedaquiline will, therefore, lead to major improvement in treatment outcomes and in the quality of life of patients.

While the new guidelines for MDR-TB treatment will be released later this year, the “rapid communication” issued by the WHO is to inform member-states to take “immediate steps” to ensure that MDR-TB patients receive treatment in accordance with the latest evidence on drug effectiveness and safety. The WHO’s interim guidelines recommended that the drug be given to MDR-TB patients only as a last resort as large-scale clinical trials (Phase III) using bedaquiline have not been carried out. In Phase IIb trials, the drug was found to have cardio-toxicity, and there were also more deaths during the trial. The formal review of the 2016 WHO guidelines was prompted by evidence of effectiveness and safety of drugs from several clinical trials, observational studies, and programmatic implementation of new regimens to treat MDR-TB patients.

South Africa was the first country to scale up access to bedaquiline. In June, South Africa said bedaquiline would replace injectables for treating all MDR-TB patients. In July, it struck a deal with Johnson & Johnson to halve the price of the drug — to $400 from about $750 — for a six-month course of treatment. The company has committed to offer the drug at $400 to India, over 50% cheaper than the earlier price of $900 negotiated with the government two years ago. As per WHO Global TB Report 2017, India had an estimated 84,000 new MDR/rifampicin-resistant-TB cases in 2016 among those notified. Based on the first-ever drug susceptibility testing on nearly 5,000 TB patients (new and previously treated) carried out in India in 2014-2016, 6.19% were found to be multidrug-resistant. India has been getting bedaquiline drug courses (11,000 so far) for free under the conditional access programme of USAID, which will end next year. With the drug becoming cheaper, and its effectiveness and safety now proven, India should waste little time to make the switch to treat all MDR-TB patients with bedaquiline.

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An urban redevelopment project must apply for approvals in an integrated manner

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