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WHO issues guidelines for drug resistant TB treatment

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The World Health Organization (WHO) has issued interim guidelines on the use of bedaquiline to treat MDR-TB. WHO estimates that up to half a million new cases of multidrug-resistant tuberculosis (MDR-TB) occur worldwide, each year. Current treatment regimens for MDR-TB present many challenges including the fact that treatment lasts 20 months or more, requiring daily administration of drugs that are more toxic, less effective, and the fact that it is far more expensive than those used to treat drug-susceptible TB. Globally, less than half of all patients who start MDR-TB therapy are treated successfully.

MSF says that the scale of the DR-TB epidemic is huge, with 310,000 new cases notified in 2011. But globally, only 19% of people thought to be infected are receiving some kind of treatment

Global NGO, Mediciencs Sans Frontiers issued a response to WHO's guidelines was which said, "The new WHO guidelines on bedaquiline use are welcomed, and are very timely given the drug's recent approval by the USFDA and the urgent need to scale-up treatment of drug-resistant TB.Regulated, controlled use of bedaquiline is essential in ensuring we don't burn one of the very few drugs available that could effectively treat drug-resistant TB."

Bedaquiline is the first drug in over 40 years, to be approved for treatment of TB drug with a novel mechanism of action. It was granted an accelerated approval by the United States Food and Drug Administration in December 2012.

There is considerable interest in the potential of this drug to treat MDR-TB. However, information about this new drug remains limited. It has only been through two Phase IIb trials for safety and efficacy. WHO is therefore issuing "interim policy guidance".

This interim guidance provides advice on the inclusion of bedaquiline in the combination therapy of MDR-TB in accordance with the existing WHO Guidelines for the programmatic management of drug-resistant TB (2011 Update). The interim guidance lists five conditions that must be in place if bedaquiline is used to treat adults with MDR-TB:

1) Effective treatment and monitoring: Treatment must be closely monitored for effectiveness and safety, using sound

treatment and management protocols approved by relevant national authorities.
2) Proper patient inclusion: Special caution is required when bedaquiline is used in people aged 65 and over, and in adults living with HIV. Use in pregnant women and children is not advised.
3) Informed consent: Patients must be fully aware of the potential benefits and harms of the new drug, and give documented informed consent before embarking on treatment.
4) Adherence to WHO recommendations: All principles on which WHO-recommended MDR-TB treatment regimens are based, must be followed, particularly the inclusion of four effective second-line drugs. In line with general principles of TB therapeutics, bedaquiline alone should not be introduced into a regimen in which the companion drugs are failing to show effectiveness.
5) Active pharmacovigilance and management of adverse events: Active pharmacovigilance measures must be in place to ensure early detection and proper management of adverse drug reactions and potential interactions with other drugs.

WHO also strongly recommended the acceleration of Phase III trials to generate a more comprehensive evidence base to inform future policy on bedaquiline. It is also developing an operational document to facilitate bedaquiline implementation and is working with partners to help ensure rational introduction.