Geneva | 13 June 2013 - 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: treatment lasts 20 months or more, requiring daily administration of drugs that are more toxic, less effective, and 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.

For the first time in over 40 years, a new TB drug with a novel mechanism of action - bedaquiline- is available, and was granted 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. The World Health Organization (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 strongly recommends the acceleration of Phase III trials to generate a more comprehensive evidence base to inform future policy on bedaquiline.

The Organization will review, revise, or update the interim guidance as additional information on efficacy and safety become available. WHO is also developing an operational document to facilitate bedaquiline implementation and is working with partners to help ensure rational introduction.