



**Survey assessing the implementation
barriers for some new drugs for treatment
of multidrug-resistant TB (MDR-TB)**

09 March 2017

Original: English with Russian translation

Scope and purpose

Title of the survey:

Survey assessing the implementation barriers for some new drugs for treatment of multidrug-resistant TB (MDR-TB)

Organized/sponsored by

The World Health Organization Global TB Programme and the World Health Organization Regional Office for Europe

Background

For the first time in nearly 50 years, two new compounds from a new drug class— bedaquiline (bdq) and delamanid (dlm) – have been approved for the treatment of tuberculosis (TB). Each is conditionally approved for the treatment of multidrug-resistant TB (MDR-TB) in cases where an effective treatment regimen is not otherwise available. Since then the two new drugs have been introduced in a number of countries under programmatic conditions or other special programmes such as expanded access or compassionate use. However, the scale up of the introduction of new drugs is slow because of some implementation barriers.

A recent study by the Global Drug Facility and MSF has identified a number of the factors that halt the improved access to the new drugs for the patients with limited options for treatment. Registration of the new drugs by the national regulatory authority has been identified as one of the main barriers.

Objectives of the survey:

The survey objective is to identify the main regulatory barriers for the registration of bedaquiline (bdq) and delamanid (dlm) in 30 MDR-TB high burden countries, and to identify areas in which the World Health Organization and its partners could provide support to countries to overcome such barriers.

Purpose of the survey

To identify challenges and possible solutions to overcome regulatory barriers for introduction of new TB medicines in the countries. The survey results will also help WHO and other technical partners to better support countries in accessing these drugs, especially for the treatment of MDR-TB patients who have limited treatment options.

Communication for the nominations

All information about the survey as well as questions and answers with regards to the survey conduct should go to Mrs. Tiziana Masini at tizianamasini@gmail.com with a copy to Dr Olexandr Polishchuk at polishchuko@who.int