



Introduction and rational use of new drugs/regimens for TB treatment

CURRENT SCENARIO

- Much progress has been made in research and development of new drugs for TB over the last decade.
- There are currently eight new or repurposed drugs in Phase I, Phase II or Phase III trials for the treatment of drug-susceptible, drug-resistant TB or latent TB infection.
- Two novel drugs, bedaquiline and delamanid, have been approved by stringent regulatory authorities under accelerated or conditional approval procedures for the treatment of MDR-TB as part of combination therapy for adults with pulmonary TB when other alternatives are not available.
- Novel drug combinations for shortened treatment of drug-sensitive and/or drug-resistant TB, including new or repurposed drugs, are under investigation in a series of Phase II and III trials with results expected in 2017.

UNMET NEEDS

- **People with drug susceptible TB** need a shorter and simpler therapy;
- **People with drug-resistant TB** need a more efficacious, fully oral, shorter, less toxic and safer therapy;
- **People living with HIV** need TB drugs with no or low drug-drug interactions with antiretrovirals;
- **People with latent TB infection** need shorter and safer therapy;
- **Children with TB** need a more child-friendly and efficacious treatment.

THE NEED FOR WHO GUIDANCE

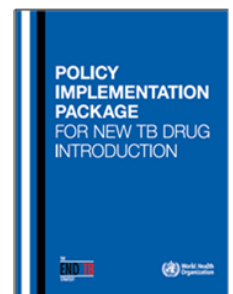
The introduction of new drugs or drug regimens for the treatment of all forms of TB has a series of public health implications, particularly regarding:

- the responsible use of new drugs as part of set combination regimens for TB treatment;
- the programmatic feasibility and cost-effectiveness of newly-developed treatments;
- the capacity to monitor scaled-up use of new drugs, and conduct surveillance of drug-resistance;
- the prevention of emergence of new drug resistance.

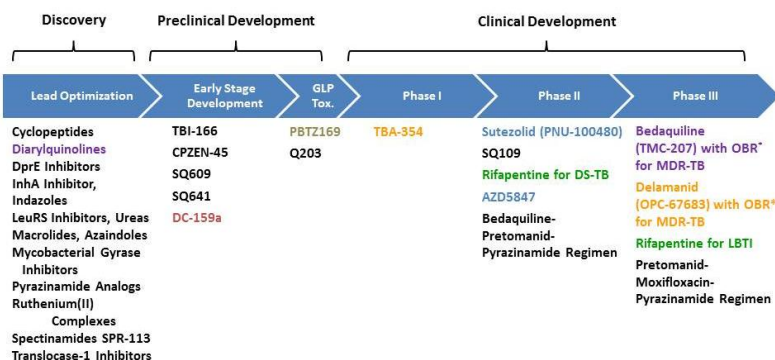
WHO STRATEGIC ROADMAP

FOR THE INTRODUCTION OF NEW TB DRUGS OR REGIMENS IN COUNTRIES

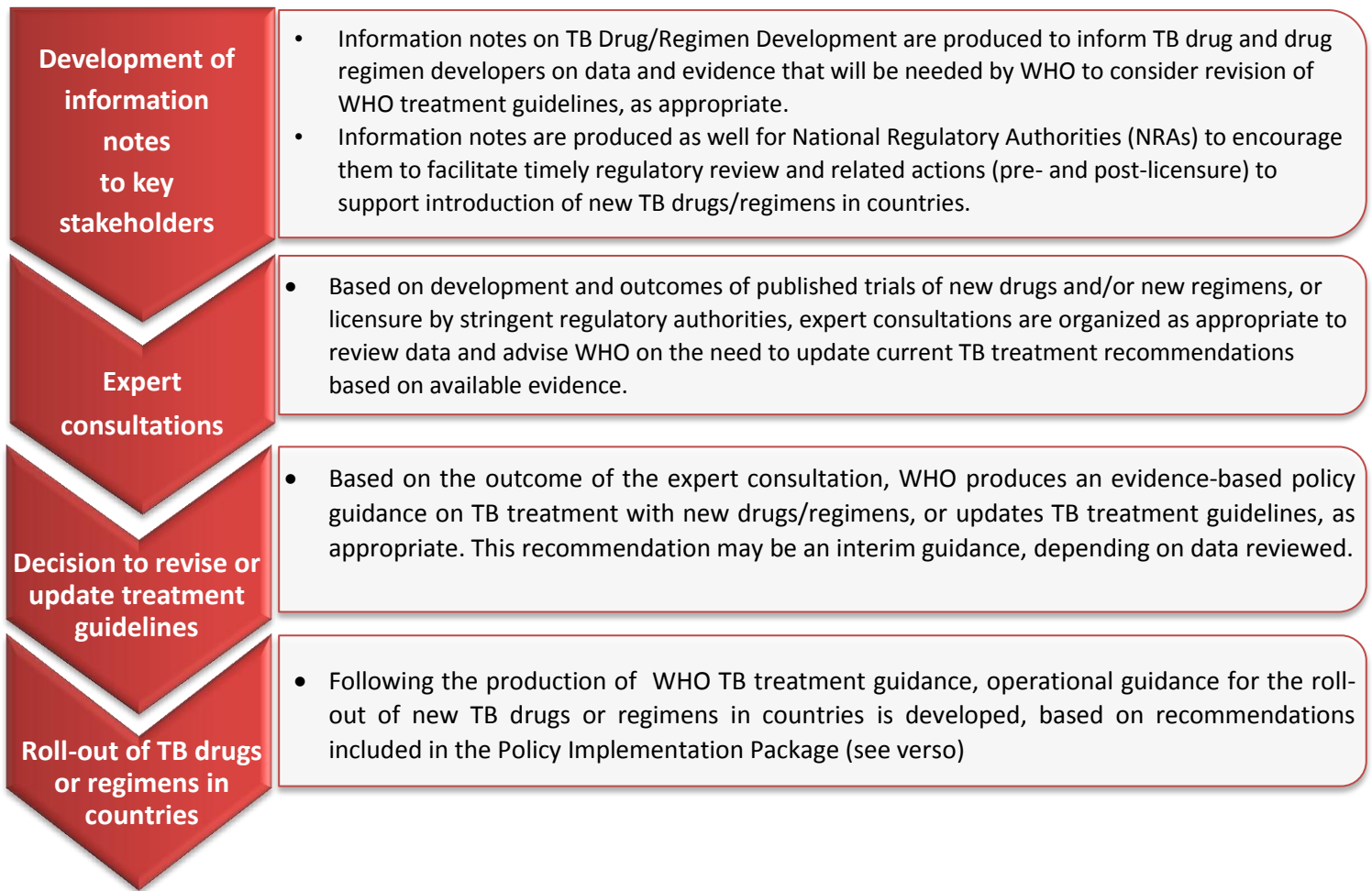
- In June 2012, the WHO Strategic and Technical Advisory Group on Tuberculosis (STAG-TB) endorsed a plan to develop updated policy guidance for TB treatment, as results of clinical trials become available and new drugs/regimens are being granted regulatory license for market access.
- This plan aims to foster optimal uptake and responsible use of new TB drugs and regimens under programmatic conditions.
- A *strategic WHO roadmap* was developed outlining the process to guide the introduction and use of new TB drugs or regimens in countries.
- A *Policy Implementation Package* was developed to assist countries in preparing for the introduction of new TB drugs and/or regimens, based on WHO policy guidance. This package addresses the specific aspects of country preparedness, safety monitoring, procurement and supply support, engagement of the private sector, and operational



THE GLOBAL PIPELINE OF NEW TB DRUGS



WHO ROLES



INTERIM GUIDANCE ON THE USE OF TWO NEW DRUGS FOR THE TREATMENT OF MDR-TB

BEDAQUILINE

WHO Interim Guidance (2013)

Bedaquiline may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB, under five specific conditions:

1. Proper selection of patients
2. Patient informed consent
3. Treatment design based on WHO recommendations
4. Close monitoring conditions
5. Active pharmacovigilance and management of adverse events

(Conditional recommendation, very low confidence in estimates of effect)



DELAMANID

WHO Interim Guidance (2014)

Delamanid may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB, under five specific conditions:

1. Proper selection of patients
 2. Adherence to the principles of designing a WHO-recommended MDR-TB regimen
 3. Treatment under close monitoring
 4. Active pharmacovigilance
 5. Patient informed consent
- (Conditional recommendation, very low confidence in estimates of effect)*

