

# NO TIME TO WAIT

## Overcoming the gaps in TB drug development

### Conference Statement

On 11-12 January 2007, Médecins Sans Frontières, supported by Weill Cornell Medical College, convened a symposium entitled *No Time to Wait* in New York aimed at stimulating efforts to accelerate the development of effective new treatments for tuberculosis (TB). The symposium brought together more than 100 experts from around the world, including drug developers, clinical researchers, health professionals, policy makers, donors, and activists.

Conference participants agreed that current approaches are inadequate to respond to the urgency of the global TB epidemic.

- TB is a global health emergency. Every year TB kills around 2 million people and 9 million develop the disease
- Almost half a million new cases of multi-drug resistance (MDR) TB are seen every year, and cases of extensively drug-resistant (XDR) TB are increasingly being detected
- TB is the leading killer of people with HIV/AIDS and the inadequacy of tools to diagnose and treat TB are a major threat to the health and lives of HIV/TB co-infected individuals
- We have inadequate and outdated tools for rapid diagnosis, inadequate and outdated drugs to cure many adults and children with TB today, and an inadequate pipeline to ensure our ability to cure the majority of TB cases in the future<sup>1</sup>
- We lack the basic biological understanding of this complex disease to anticipate the most efficient routes to prevent and treat TB
- Clinical trials for drugs and combinations that could be done today are being held back because of a lack of funding and capacity as well as regulatory barriers
- Meaningful gains in TB control will only be made when the treatment of TB, including drug-resistant TB, can be dramatically shortened and simplified

Participants call upon governments, intergovernmental agencies, researchers, drug and diagnostic developers, nongovernmental organizations, and funders to take action in five key areas.

#### **1. Accelerate drug discovery**

- The public and not-for-profit sector needs to be guaranteed access to professional pharmaceutical services, which mostly exist in the private sector, to develop diagnostics and drugs. Mechanisms must be established to ensure public access to compound libraries and to build appropriate libraries with potential to exhibit anti-TB properties, particularly novel and natural products

## **2. Expand clinical trial capacity and accelerate clinical development**

- Worldwide, only \$20 million is spent annually for clinical trials for TB drug compared to around \$300 million for HIV drugs in the US alone.\* Funding bodies should support the creation of a TB clinical trial platform and the massive expansion of clinical trial capacity, particularly in developing countries
- There is an immediate priority to shorten the time of clinical drug development. Criteria for compassionate use must be established by the WHO and regulatory authorities for important candidate drugs
- In particular, trials for (M)DR-TB drugs must be prioritized because of the explosive spread of drug resistance and the potential of these trials to show efficacy rapidly
- Drug trials should seek to integrate studies of potential new diagnostics

## **3. Support new approaches to R&D**

- The lack of TB drug development is a result of the failure of current profit-driven drug research and development model. The TB community must engage in the World Health Organization's Intergovernmental Working Group on Innovation, Intellectual Property and Public Health to establish a global R&D framework to help design new ways of setting R&D priorities and financing.
- With respect to TB drug development, participants of the New York symposium support current discussion at the WHO for a treaty on essential health R&D that addresses the question of who pays for essential medical R&D and de-links incentives from drug prices, instead rewarding the impact of inventions according to health care outcomes.

## **4. Commit to global TB R&D leadership**

- Strong political leadership is required to improve collaboration among scientists, drug developers, care providers, and affected individuals, in both developed and developing countries, and develop a global priority research agenda for TB

## **5. Increase funding for TB R&D activities**

- There is a critical funding gap for TB R&D. Around \$900 million needs to be invested annually in the development of new tools for TB, but only \$206 million was invested in 2005, and the funding gap is expected to widen over time.\* A dramatic funding increase is needed to support drug research and development activities. This is above all a matter of political prioritization.

\*Feuer C. Tuberculosis research and development: a critical analysis. Treatment Action Group, New York, October 2006

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<sup>i</sup> Casenghi M, von Schoen-Angerer T. Development of New Drugs for TB Chemotherapy. Analysis of the current drug pipeline. MSF 2006