

# The Cape Town Declaration

## The Cape Town Declaration of the Working Alliance for TB Drug Development, Cape Town, South Africa, February 8th, 2000

*Signatories include the American Lung Association, American Society for Tuberculosis Education and Research, American Thoracic Society, Association of the British Pharmaceutical Industry, Bill & Melinda Gates Foundation, Boston Consulting Group, European Commission, Global Forum for Health Research, International Union Against Tuberculosis and Lung Disease, Lupin Laboratories, Médecins Sans Frontières, Medical Research Council of South Africa, Novartis India Ltd, Partners in Health, Research Triangle Institute, Rockefeller Foundation, Royal Netherlands Tuberculosis Association (KNCV), Sequella Global Tuberculosis Foundation, Stop TB Initiative, TDR (Tropical Diseases Research), U.K. International Development Secretary, U.S. Agency for International Development, U.S. Centers for Disease Control, U.S. National Institutes of Health, U.S. National Tuberculosis Center, Wellcome Trust, World Bank, and the World Health Organization.*

The Working Alliance for TB Drug Development, a group of interested organizations, meeting in Cape Town, this Eighth day of February in the year Two Thousand,

Expressing the need to accelerate the development of new drugs to shorten the treatment of tuberculosis (TB) and facilitate its control in the poorest countries,

Hereby makes the following declaration:

### I

The increasing TB burden is a blot on the consciousness of human kind. One third of the world's population, 2 billion people, are infected with *M. tuberculosis*. Today, there are 16 million patients with active TB, and every year there are 8 million new cases, and 2 million deaths; one third of all HIV-positive people die with TB;

### II

TB is a marker of social inequity and a serious impediment to economic development. As poverty fuels TB, so does TB fuel poverty. Globally, TB is a leading killer of young adults. TB is also a major cause of death in women of childbearing age. Although, 95% of this burden falls in poor countries (in India alone, TB kills one person every minute), TB is a global problem that knows no borders;

### III

TB treatment is one of the most cost-effective health interventions and DOTS (Directly Observed Therapy, Short Course) is currently the best strategy to deliver it. As one person with TB can infect many others, early diagnosis and treatment are an effective preventive strategy, together with the treatment of latent infection. Such interventions are also an efficient intervention to extend and improve the lives of HIV-positive people.

We, recognizing the above, draw attention to the following challenges and opportunities:

### IV

After a decade of global efforts under the World Health Organization's (WHO) leadership, DOTS coverage expanded significantly. Despite this public health achievement, less than half of patients are detected by the health care system. Of those patients who are found to have the disease, nearly half cannot complete therapy, thus ensuring ongoing transmission and the emergence of multi-drug resistance (MDR-TB);

### V

Implementation of TB control remains a challenge. Treatment duration of at least 6 months requires infrastructure and managerial skills often insufficient in the very areas most affected by TB. In settings where TB control is weak, compliance with treatment drops dramatically after 2 months. Furthermore, a quarter of all TB patients will go without therapy in the year 2000 due to geographic, financial and other programmatic barriers;

### VI

To scale up DOTS implementation we need both more effective use of existing tools and new products. No new drugs to fight TB have been introduced in decades. BCG was developed in the early 20th century but its effectiveness is limited and, despite widespread use, it has not stopped the epidemic. Substantial efforts are currently underway to develop an effective vaccine but it may take another 20 years before it becomes available. During that time 50 million people will die from TB;

## VII

In the 1960s and 1970s, the duration of TB chemotherapy was shortened from 24 to 6 months after the introduction of novel drugs. Further shortening TB treatment would be another revolution in endemic countries, potentially leading to improved compliance and cure rates, decreased program costs, and expanded DOTS coverage, making sustainable TB control a reality. New drugs should also help overcome MDR-TB, and more efficient treatment of persons with latent TB infection could be instrumental in eliminating TB in many countries;

## VIII

The recent sequencing of the *Mycobacterium tuberculosis* genome and the biotechnology revolution offer solid opportunities for TB drug development. New compounds are needed, but TB drugs could emerge as derivatives of current TB drugs or from other antibiotics. The effort should bear fruit within this decade;

## IX

A new drug need not necessarily be a substantial financial burden on a country's health budget. For example, shortening treatment to 1 or 2 months would free up the cost of drugs of the remaining 4 to 7 months. There are other potential savings in drug delivery costs, plus the economic, social and humanitarian benefits of improved TB control;

## X

Approximately 10 million patients are treated for TB every year. At an average drug-cost of \$50 per treatment, annual drug sales are considerable. A company introducing a new drug could share a substantial portion of that market. Furthermore, drug development costs would be shared by the public sector (drug screening and clinical trials.) Need and consensus would expedite drug registration, and market penetration should occur fast and without costly marketing.

## **We commit ourselves to accelerate the development of new TB drugs to improve the prevention and treatment of the disease.**

In coming months we will:

- ◆ **W**ork in concert with the goals for TB control as outlined by the Stop TB Initiative, a global partnership coordinated by the World Health Organization which recognizes the need for new tools as part of a comprehensive approach to fight TB.
- ◆ **L**ay out a Scientific Blueprint for TB Drug Development that brings technical consensus by existing institutions and clarifies priorities for academic research and coordinated funding over the next 5 to 10 years;
- ◆ **P**ut together a Report on the Pharmaco-economics of TB Drug Development that clarifies the size and characteristics of TB drug markets, the cost, current investment and gaps in research and development, and the social and financial returns of a new TB treatment by the year 2010 taking into account the evolving epidemics of HIV and MDR-TB;
- ◆ **D**esign the Road Map for Advocacy for the Development of New TB Drugs to bring about support and resources for this initiative, and to ensure its products reach all patients.
- ◆ **D**evelop a dedicated Global Alliance for TB Drug Development with partners from academia, industry, major agencies, non-governmental organizations, and donors the world around.

Acknowledging a variety of efforts and institutional missions, this partnership will provide leadership, raise funds, advocate, and coordinate efforts in various sectors and settings to improve health equity by developing and delivering a simple and affordable TB treatment in endemic countries this decade.

*This declaration reflects the spirit of participants in the meeting of Cape Town on TB Drug Development, February 6-8, 2000. The meeting was convened by the Rockefeller Foundation, hosted by the Medical Research Council of South Africa, and co-sponsored by the Stop TB Initiative, the U.S. National Institutes of Health, the Bill and Melinda Gates Foundation, the Wellcome Trust, and the U.K. Department of International Development.*