1. WHAT IS THE GDF?

Future generations will no doubt ask us why we continued to allow two million people to die every year from a disease that can be cured with drugs that cost only US$ 10. They will rightly question our commitment, our priorities, our sense of justice, and our understanding of human rights.

Dr J W Lee, Director Stop TB

The Global Drug Facility (GDF) is a new initiative of the Stop TB Partnership to increase access to high-quality tuberculosis (TB) drugs. The aim of the GDF is to provide drugs for 10 million patients over the next five years, and to treat 45 million patients over a 10-year period. WHO has called for a commitment to this initiative of at least US$ 250 million by 2005.

• Tuberculosis is the world’s leading curable infectious killer. Every day, 20,000 people develop active TB and 5,000 die from their disease. Without treatment, about 70% of people with TB will die. If left untreated, a single person with infectious TB can infect between 10 and 15 people each year.

• The global TB epidemic increased 6% between 1997 and 1999, largely due to a 20% increase in African countries affected by the HIV/AIDS epidemic. If these trends continue, 10.2 million new cases a year are expected by 2005.

• The continued growth of this epidemic is totally unnecessary and completely avoidable. DOTS—the internationally recommended control strategy for TB—has long been proved to cure patients, save lives, prevent the spread of drug resistance, and reduce transmission of the disease.

• Progress in expanding DOTS remains inadequate. The World Health Organization (WHO) has estimated that only 23% of people with infectious TB are treated in DOTS programmes. Unless there is a rapid acceleration of DOTS expansion, the global targets of detecting 70% of people with infectious TB and curing 85% of those detected will not be met until 2013.

• A significant barrier to rapid DOTS expansion is drug shortages. A 6-month course of treatment for TB costs as little as US$ 10. Nevertheless, shortages of TB drugs are frequent and serious in many parts of the world and are most often caused by financial constraints, inefficient drug procurement systems, and poor management.
• The Global TB Drug Facility is not a storage facility, but is a “virtual” organization designed rapidly and efficiently to provide grants-in-kind of essential TB drugs to countries in need. The GDF reviews applications from countries, and contracts with procurement agents to provide high-quality TB drugs for use in DOTS programmes.

• With an initial contribution from the Canadian International Development Agency (CIDA), the GDF was launched on 21 March 2001 and has already approved grants to 12 countries in Africa, Asia, and Eastern Europe. Within its first year of operations, the GDF will have provided drugs for nearly half a million TB patients.

• Although developing countries, which carry over 90% of the global TB burden, are the main beneficiaries of the GDF, industrialized countries will also benefit from the support the GDF provides. As the global population becomes more mobile, national borders present no obstacle to the spread of TB. Outbreaks of infection acquired during air travel are a growing hazard, sometimes involving multidrug-resistant TB (MDR-TB), a form of the disease that is expensive and difficult to cure. Investing in the GDF is not just a humanitarian responsibility for the developed nations: it makes good public health sense.

• The GDF is managed by the Stop TB Partnership Secretariat in WHO Headquarters, Geneva. The goals of the GDF are:
  a) to ensure uninterrupted access to quality TB drugs for DOTS implementation;
  b) to catalyse rapid DOTS expansion in order to achieve global targets for TB control;
  c) to stimulate political and popular support in countries worldwide for public funding of TB drug supplies;
  d) to secure sustainable global TB control and eventual elimination.

• The GDF is a partnership initiative and relies heavily for continued technical, logistic, and financial support from the many Stop TB partners. These include the Dutch government, the International Union Against Tuberculosis and Lung Disease (IUATLD), the Management Sciences for Health (MSH), the Rockefeller Foundation, the Royal Netherlands Tuberculosis Association (KNVC), the UNDP Inter-Agency Procurement Services Office (IAPSO), and the World Bank.

• Through standardization of drug products, a bulk buying procurement system and competitive bidding processes, the GDF has slashed TB drug prices for a six-month course of treatment to just US$ 10, a reduction of 30% compared to previous international drug prices. As a result of achieving these prices, the total cost of treating the 11.6 million additional cases need to reach the global targets for TB control by 2005 amounts to US$ 133 million, compared to US$ 280 million at previous international prices—a potential saving of US$ 147 million over the next five years.

• Following two rounds of applications review, 12 countries have already been approved for GDF support. These are: Democratic People’s Republic of Korea, Kenya, Liberia, Myanmar, Pakistan, Republic of Congo (Brazzaville), Republic of Moldova, Somalia, Sudan, Tajikistan, Togo, and Yemen.
2. HOW DOES THE GDF WORK?

The Global Drug Facility (GDF) is a new initiative of the Stop TB Partnership, managed by the World Health Organization (WHO). The aim of the GDF is to provide tuberculosis (TB) drugs to treat about 10 million patients over the next five years, to accelerate DOTS expansion, and to meet the global targets for TB control by 2005.

• The GDF was established in response to a call from the Ministers of Health, Finance and Development Planning from 20 countries at the conference on Tuberculosis and Sustainable Development held in Amsterdam, Netherlands, in March 2000. The GDF became operational in January 2001 with initial funding of US$ 10 million from the Canadian Government. Drug procurement has been initiated through the Inter-Agency Procurement Services Office (IAPSO), which is part of the United Nations Development Programme (UNDP).

• The operating principles of the Global TB Drug Facility include independence, transparency, accountability, flexibility, rapidity, and responsiveness. The GDF seeks to achieve substantial economies of scale through pooled demand forecasting, standardization of regimens, pre-qualification of manufacturers, bulk purchasing and reduced transaction costs.

• Governments and nongovernmental organizations (NGOs) that follow the diagnostic, treatment and monitoring policies of DOTS are eligible to apply for grants of TB drugs from the GDF.
The GDF has a five-step procedure for making grants:

1. Applications
   Countries and NGOs complete the application forms sent to them by the Stop TB Partnership Secretariat through WHO's regional offices and via the Stop TB website. Applications are prepared in collaboration with the agency that usually provides technical support for TB control in that country.

2. Review of applications
   The Technical Review Committee (TRC) of the Global TB Drug Facility is a group of independent experts in TB control, drug management, and TB programme management from around the world. The TRC regularly reviews applications from countries and makes recommendations on grants to countries. In cases where conditions for GDF support have not been fulfilled, the TRC will advise countries on the measures needed to ensure their eligibility for grants in the next round. GDF support to a country is usually approved in principle for three years.

3. Country visit
   The Stop TB Partnership Secretariat arranges a country visit in order to:
   - brief senior government officials and other stakeholders on the role of the GDF;
   - explain the implications of a grant from the GDF;
   - confirm fulfilment of the conditions for support from the GDF;
   - clarify quantities of drug required;
   - assess the current TB drug procurement and distribution system within the country.

4. Procurement
   WHO has appointed a procurement agent (currently UNDP/IAPSO), selected through a process of competitive bidding to manage the supply process. These include: procurement, pre-shipment inspections, laboratory analysis, shipping and insurance.

   IAPSO coordinates the services of other selected agents for pre-shipment inspection, laboratory analysis, freight, and insurance. The drugs identified, specified and quantified by the GDF are tendered through Limited International Competitive Bidding (LICB) to a list of pre-qualified suppliers, and purchased for direct shipment to the recipient country. All shipments are subject to a pre-shipment inspection with laboratory analysis of drugs.

   UNDP/IAPSO provides a web-based system for the tracking of orders at http://www.unwebbuy.org. Up to date reports on the progress of every step in the supply chain, including delivery, are available to the recipient country and to the Stop TB Partnership Secretariat.

5. Monitoring
   Continued support from the GDF is conditional upon:
   a) continued fulfillment of GDF conditions;
   b) submission of satisfactory annual reports;
   c) submission of requests for drugs;
   d) availability of GDF resources.

   The agency that usually provides technical support to the country (e.g. the International Union against Tuberculosis and Lung Disease (IUATLD), the Royal Netherlands TB Association (KNCV), or WHO) will continue to carry out regular monitoring within the country. Each country submits these routine monitoring reports to the Stop TB Partnership Secretariat along with a request for drugs. (WHO contracts with a technical agency or agencies (selected through competitive tendering) to provide independent assessment of these monitoring reports, to ensure fulfilment of GDF conditions.)

   The TRC reviews the monitoring report and recommends continuation of support.