



BACKGROUND ON THE LILLY MDR-TB PARTNERSHIP

About The Lilly MDR-TB Partnership

The Lilly MDR-TB Partnership was created to help contain and ultimately conquer multidrug-resistant tuberculosis (MDR-TB), a disease so daunting that no single organization can fight it alone. The Partnership, a public-private initiative, mobilizes 18 partners on five continents in the battle to stop the spread of MDR-TB and save lives. Lilly is donating \$135 million in cash, medicines and technology to increase access to treatment and focus global resources on prevention, diagnosis and treatment of patients with MDR-TB.

The Lilly Partnership initiatives all have one thing in common: improved care for some of the world's most vulnerable people, who are least able to fight this disease. The public-private partnership provides access to medicines, transfers manufacturing technology to the developing world, trains healthcare workers, raises awareness and promotes research and prevention, while providing support for communities and advocating on behalf of patients. The partners work together closely, sharing knowledge, expertise and research in the quest to contain and conquer one of the world's oldest diseases. The Lilly MDR-TB Partnership is about more than the transfer of technology and know-how — it's the *Transfer of Hope*.

About the Transfer of Technology

The Partnership is overseeing the transfer of technology and expertise to manufacture Lilly's two antibiotics for MDR-TB, capreomycin (Capastat[®]) and cycloserine (Seromycin[®]). Since 2003, Lilly has transferred technology, formulas and trademarks to manufacturers in South Africa, China, India and Russia — some of the world's highest-burden countries.

This unique approach not only allows patients to access medicines at lower prices, but also supports local economies and the manufacturing of high-quality medicines. Lilly supplies manufacturing know-how, financial assistance to purchase manufacturing equipment, and training on Good Manufacturing Practices, which raises the overall standards of safety for the production of these medicines. Lilly has negotiated agreements with the companies participating in the technology transfer, including how much may be charged for products to be used in treatment programs sponsored by the World Health Organization (WHO) and other donor organizations.

Meanwhile, Lilly continues to supply both capreomycin and cycloserine at concessionary prices to WHO-approved DOTS programs (Directly Observed Treatment, Short-course) for MDR-TB. Under DOTS, supervisors observe the patients while they are taking their medications for the duration of their treatment. These medicines are supplied through the WHO's Global Drug Facility.



Lilly has shipped some 1.3 million vials of capreomycin and 5.5 million capsules of cycloserine through the WHO DOTS program to patients in 42 countries.

About the Partners

- **Aspen Pharmacare**, the technology transfer partner in South Africa, sold its first batch of cycloserine to Botswana in 2006, and is now producing cycloserine in a brand new facility in Port Elizabeth, South Africa, with a capacity of 4 billion capsules per year. Aspen is working with the WHO to begin supply to countries approved by the Green Light Committee (GLC), a procurement vehicle for purchasing second-line medicines at reduced prices. Aspen also has begun construction of a facility at the Port Elizabeth site to produce vials of capreomycin in early 2009.
- **Eli Lilly and Company**, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, USA, Lilly provides answers -- through medicines and information -- for some of the world's most urgent medical needs.
- **Harvard University and Partners in Health (PIH)** have established a Center of Excellence for MDR-TB treatment and training in Tomsk, Russia. Several hundred doctors, nurses and healthcare workers from cities all over Russia and the countries of the former Soviet Union already have been trained on how to prevent, detect and treat MDR-TB. PIH and Russia's five Tuberculosis Research Institutes (TBRI) have been working together since 2006 to develop the first national MDR-TB training standards. PIH also has established an MDR-TB Advisory Board in Russia consisting of public health officials, international organizations and members of academia. Russian doctors have been sent to Harvard University's School of Public Health to participate in Clinical Effectiveness Programs that include training in healthcare measurement and research design. PIH also is working on an anti-alcohol campaign in Russia, since alcoholism has been found to be a major factor in treatment non-compliance.
- **Hisun Pharmaceutical**, the technology transfer partner in China, produced its first batch of the active ingredient for capreomycin in May 2006. Hisun also is building another facility to produce vials of the capreomycin product in 2009.
- **The International Council of Nurses (ICN)** has launched a global project to equip nurses around the world with the knowledge and tools for detection, treatment and management of TB/MDR-TB. ICN has published a set of guidelines for nurses and has established a Web-based "Global TB/MDR-TB Resource Centre" for 13 million nurses working worldwide. In 2005, ICN launched its TB/MDR-TB train the trainers initiative for nurses in South Africa and the Philippines. The organization also has implemented the program in Lesotho, Malawi, Russia, Swaziland and Uganda. More than 200 nurses in these countries have been trained and will be training their colleagues. ICN also has developed an anti-stigma toolkit



entitled “TB and Stigma: A Double Burden,” since removing the stigma encourages people to seek treatment.

- **The International Federation of Red Cross and Red Crescent Societies (IFRC)** has implemented TB-patient support programs aimed at the most vulnerable populations, including homeless people and those suffering from alcoholism and drug addiction. The programs, which include public awareness and anti-stigma campaigns, community outreach, psychological support and food aid, are now underway in Kazakhstan, Romania and Uzbekistan. IFRC volunteers have a long tradition of working with at-risk populations in some of the world’s most impoverished nations.
- **The International Hospital Federation (IHF)** has developed a comprehensive TB/MDR-TB-control training manual for hospital managers in IHF’s 40,000 public and private hospitals and clinics. The goal of the manual is to provide much-needed support to hospital staff that diagnose, treat and manage TB/MDR-TB patients. The manual, which was tested in South Africa in 2006, also will serve as a guide to infection control, thereby helping to fight a growing health threat in hospitals and clinics in developing countries.
- **Purdue University** assists in the transfer of technology and trains partner companies in Good Manufacturing and Business Practices. The Indiana-based University also will produce cycloserine in its new plant, the Chao Center for Industrial Pharmacy in West Lafayette, and has submitted a request to the U.S. Food and Drug Administration seeking approval to manufacture the medicine. Purdue and Lilly are working with the government of Kazakhstan to train drug inspectors in Good Manufacturing Practices to enhance the quality of all medicines produced there.
- **RESULTS Educational Fund** is a nonprofit grassroots advocacy organization committed to creating the political will to end hunger and the worst aspects of poverty. Working with activists in the U.S. and in affected countries around the world, RESULTS advocates for increased resources and action to stop TB.
- **Shasun Chemicals and Drugs**, the technology transfer partner in India, dispatched its first order of the active ingredient for cycloserine in February 2006 to Aspen Pharmacare, which will formulate the finished product. Shasun also received registration approval for the cycloserine active ingredient in the U.K., and is working with Purdue University to develop a plan to seek approval from the U.S. Food and Drug Administration. In addition, Shasun has partnered with a local Indian hospital and Rotary International to develop a TB screening program.
- **SIA International/Biocom** is one of Russia’s largest pharmaceutical companies and is Lilly’s newest technology transfer partner. SIA will produce both capreomycin and cycloserine by late 2007.
- **Stop TB Partnership** was established in 2000 to realize the goal of eliminating TB as a public health problem and, ultimately, to obtain a world free of TB. It comprises a network of international organizations, countries, donors from the public and private sectors, governmental and nongovernmental organizations and individuals that have expressed an interest in working together to achieve this goal. Stop TB has launched an award for reporting on TB and is leading a global campaign featuring well-known TB ambassadors to raise awareness on the disease.



- **TB Alert** is a UK-based charity focused on patient advocacy and raising public awareness of TB. The group has joined forces with Paul Thorn, an MDR-TB survivor and author of *The TB Survival Handbook*, to launch www.tbsurvivalproject.org, an advocacy website. The website provides information and resources, and allows patients to connect with one another. Since TB patients are often isolated to prevent the spread of this highly contagious, airborne disease, Thorn seeks to provide a virtual meeting room for TB and MDR-TB patients.
- **The Advocacy Partnership** plays an active role in raising awareness about TB and MDR-TB. It circulates country-specific information about TB/MDR-TB, publishes self-help materials and offers one-to-one patient mentoring through its Tuberculosis Survival Project website.
- **The U.S. Centers for Disease Control and Prevention (CDC)** has developed a cutting-edge laboratory information management system for MDR-TB, which will soon be implemented in Russia. This new system will enable counting, monitoring and reporting of confirmed TB cases, including drug-resistant strains, much faster, more easily and more accurately than with traditional methods. At the moment, 30,000 TB lab reports are processed by hand every year in any given region of Russia. The new system could also be used by other countries to standardize TB data collection and analysis methods — a major step in conquering the disease.
- **The World Economic Forum (WEF)** has spearheaded the creation of the Business Alliance to Stop TB in India in an effort to raise awareness and improve early detection of TB. The program recognizes the crucial role the business community can play in improving public health. It seeks to help both employers and employees identify the early signs of infection and know where to go for diagnosis and treatment, and attempts to remove the stigma of TB. In collaboration with Lilly and ICN, the WEF's Global Health Initiative has developed a toolkit for businesses, with guidelines and case studies in both English and Hindi. The toolkit will be adapted for use in China and South Africa.
- **The World Health Organization (WHO)** has developed and oversees the DOTS program for the management and treatment of MDR-TB. Under DOTS, specific policies and strategies must be in place to ensure the best possible way to control the spread of resistant strains and the misuse of medicines. The program requires that a supervisor directly observe patients while they are taking their medication during treatment. This strategy is the cornerstone of the global fight against the MDR-TB pandemic. The WHO helps countries develop national programs within the approved treatment guidelines by training health-policy consultants and TB specialists, and through Drug-Resistance Surveillance (DRS) programs to monitor the evolution and spread of MDR-TB. The WHO also is part of the GLC. So far, about 26,000 patients have enrolled in DOTS programs. Lilly offers the GLC its two MDR-TB medicines at concessionary prices. The WHO provides technical assistance and training in the appropriate use of antibiotics to countries developing their own DOTS programs. The WHO also has developed software to help standardize the collection of data on patient outcomes at WHO-approved treatment sites as a way of improving TB treatment and better forecasting medicine needs.



- **The World Medical Association (WMA)** is developing a free, Web-based MDR-TB learning course for physicians in order to provide access to the latest international protocols for MDR-TB prevention, treatment and management. The Internet course, which will provide links to relevant international policy and clinical guidelines, will facilitate self-study. The course will be offered in English, Spanish, Chinese and Russian. The WMA is joined in this effort by South Africa's Medical Research Council and Foundation for Professional Development, as well as the Norwegian Medical Association, which will provide accreditation for Continuing Medical Education.