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Mr. Doug Clark
Director, Patent Policy Directorate
Industry Canada
235 Queen Street
Ottawa, ON K1A 0H5

Ms. Brigitte Zirger
Director, Therapeutic Products Directorate
Health Canada
1600 Scott Street
Ottawa, ON K1A 0K9

Review of Canada's Access to Medicine Regime

Dear Ms. Zirger and Mr. Clark,

Thank you for the opportunity to respond to the government consultation on the review of *Canada's Access to Medicine Regime*. Eli Lilly Canada Inc, along with Rx and D member companies, supported the principles of CAMR and worked collaboratively with a number of government departments, members of parliament, ministers and their staff and the Prime Minister's office to make Bill C9 a reality.

At that time, access to medicine was being identified as the sole solution to the AIDS crisis in the developing world and the pharmaceutical industry was being portrayed as the villain in this debate.

Instead of understanding the real problems associated with AIDS, malaria and TB and working on a number of integrated solutions, Canada made a decision to override patents to enable a flow of cheaper generics to countries in need.

Two years later nothing has happened, nor has anything happened in other countries with similar legislation.

Now we are asking questions again about how to make it simpler and easier to ship drugs from Canada and we may be missing the point. Questions posed are around the technicalities of the Bill, but maybe we should be asking:

- Why haven't countries requested a supply?
- Why haven't generic companies embraced this opportunity and worked with NGOs and the government to make cheaper drugs available? Is there a willingness to do so? After all, the generic associations did testify that their companies would have to make money to do so
- Can they compete with other generic companies in other parts of the world?
- Is the government willing to subsidize generic companies to help them compete with companies located in India and South Africa?
- Should Canada have a more integrated policy in dealing with diseases in developing countries?

Access to medicines in the fights against AIDS is extremely important, but access to clean water, public health, transportation to and from clinics, nurses, education and compliance are equally important.

CAMR is new legislation that is balanced and fair and may just need time. To make any substantive changes at this stage would be unfortunate.

Specific questions:

Eligible importers

- There may be an opportunity to clarify language and provide education to countries interested in participating. Purchasing by one country and re-exporting to others does increase the risk of diversion and resale.

Eligible products

- Schedule 1 is appropriate and necessary to avoid delays. The WTO decision was to deal with serious health problems and the drugs needed to treat them. It was never intended to provide any drug for any condition. To do so would certainly lead to abuse of the system.
- Part of legislation allowed for creation of an advisory committee to review which drugs should be added. The criteria should remain for serious diseases that have deadly consequences in the least developed countries.

Notification

- There needs to be some documentation of a request. A certified copy seems to be fairly minimal. This should not be seen as a roadblock if the intent is for humanitarian reasons.
- A requirement to agree that the product will not be used for commercial purposes or diverted is reasonable.

Review by Health Canada

- It is Health Canada's view that drugs leaving Canada should be reviewed and approved. If approvals are required for Canadian citizens, the people living in the developing world should not be held to a different standard.

Application Process

- How can minimal and reasonable requirements with a 30 day turnaround pose a barrier?
- Health Canada has done a lot of work on this issue to make it as simple as possible.

Duration of License

- This should be tied to the intent and requirement to prevent diversion. If so, licenses could be extended to 5 years with a review at 24 months to ensure system is not being abused.

Royalty

- At 2%, it is doubtful this would be seen as a barrier.

Good Faith Clause

- There is a fair amount of flexibility here and this should not be a barrier.

Quantities Exported

- Diversion continues to be a concern. There should be some safeguards and due diligence by Health Canada. This could be reviewed as Canada and other countries gain some experience with the regime.

Antidiversion

- This is the most important provision in the legislation and every effort should be made to ensure diversion does not happen. Diversion is already an issue in many countries, preventing patients from getting access to medicines.
- The grounds for termination of contract are very clear and fair.

Lilly

I have included with this submission Lilly's Global Partnership on Multi-Drug Resistant Tuberculosis, which can be fatal in patients with co-morbidities like AIDS and malaria.

I appreciate the opportunity to participate in this consultation. We are disappointed after so many good intentions that countries in need would request supplies and Canadian generic companies would respond to these requests. Maybe two years is a little ambitious and more time is needed for countries to be aware of the system.

I think it would be very prudent for the government to maintain the reasonable checks and balances in the legislation.

Sincerely,

Terry McCool
Vice President, Corporate Affairs
Eli Lilly Canada Inc.
Tel: (416) 699-7309

Enclosure: 1

Multi-drug resistant tuberculosis

The Lilly MDR-TB Partnership

The Lilly MDR-TB Partnership is a pioneering initiative led by Eli Lilly and Company that will increase the number of trained medical personnel and drugs available to treat people with multi-drug resistant tuberculosis, an expanding global health crisis. Described as a new paradigm for addressing global public health threats, the Lilly MDR-TB Partnership is an example of our ongoing commitment to provide "Answers That Matter."

Lilly

Answers That Matter.

The Lilly MDR-TB Partnership was announced in June 2003 by Lilly, the World Health Organization (WHO), Harvard/Brigham and Women's Hospital/Partners In Health (Harvard/BW/PIH), the Centers for Disease Control and Prevention (CDC), Purdue University, and the International Council of Nurses to address the expanding crisis of multi-drug resistant tuberculosis. Components of this pioneering effort include:

- transferring technology to manufacture two antibiotics necessary for treatment of MDR-TB in nations where the disease is most prevalent
- developing a training program and providing certification of sound business management and good manufacturing practices for each facility receiving manufacturing technology
- doubling Lilly's production of an essential drug used to treat MDR-TB
- providing both Lilly antibiotics used to treat the illness at a fraction of their cost to WHO-approved "DOTS-Plus" treatment programs
- supporting WHO's global monitoring of MDR-TB and technical assistance for MDR-TB treatment programs
- supporting the CDC's monitoring of MDR-TB
- expanding the Harvard/BWH/PIH MDR-TB training and research program in Boston, Massachusetts, and Tomsk, Siberia
- developing guidelines and best practices for treating TB and MDR-TB for nurses around the world.

Lilly's total contribution to this effort is valued at $70 million (USD) through 2006.

WHAT IS MDR-TB?

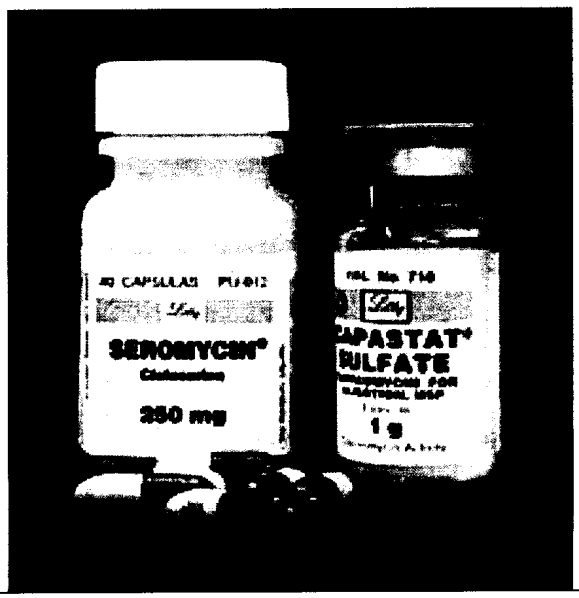
Multi-drug resistant tuberculosis (MDR-TB) is a type of tuberculosis that often develops in patients who do not complete the proper treatment for TB. This can occur when a physician does not prescribe proper treatment regimens or when a patient is unable to adhere to therapy with first-line drugs. Once a strain of MDR-TB develops, it can be spread to others just as "normal" TB. However, MDR-TB is most likely to occur among patients in developing nations where trained medical personnel and drug supplies are limited. Each year, roughly 300,000 new cases of MDR-TB occur in more than 100 countries. The WHO estimates that the average MDR-TB patient infects up to 20 other people in his or her lifetime.

MDR-TB is especially threatening because without proper treatment, super-resistant strains can emerge for which there currently is no cure.

"Though little known, MDR-TB represents one of the most severe threats to public health today. Without proper treatment and surveillance now, MDR-TB can easily become a global health emergency in years to come," said David Heymann, M.D., executive director of communicable diseases at the WHO. "Eli Lilly and Company has offered an effective model that leverages the capabilities of organizations best able to ensure the diagnosis, treatment, and surveillance of MDR-TB in areas of the world where it is most prevalent and prevent a more widespread outbreak of this dangerous disease. This public-private enterprise represents a new paradigm for addressing global public health problems."

TWO LILLY DRUGS TREAT MDR-TB

Over the past five years, Lilly supported the efforts of Jim Kim, M.D., Ph.D., advisor to the director general of the WHO, and Paul Farmer, M.D., Ph.D., chief of the Division of Social Medicine and Health Inequalities at Brigham and Women's Hospital, co-founders of Partners In Health, for their treatment of patients with MDR-TB in Peru. Their groundbreaking work, published in the *New England Journal of Medicine* (NEJM 2003, 348; 2, 119-128, Jan. 9, 2003), has convincingly established that MDR-TB can be effectively treated. Based upon such experience, as well as that in other countries, the WHO has promoted a DOTS-Plus strategy, including Capastat® (capreomycin) and Seromycin® (cycloserine), two Lilly antibiotics, for treatment of MDR-TB. DOTS-Plus is an extension of the WHO's DOTS program (Directly Observed Therapy—Short course), an intensive six-month regimen for the treatment of "normal" TB. DOTS-Plus is an 18- to 24-month treatment protocol, often requiring daily dosing of Capastat and three-times daily dosing of Seromycin.



MANUFACTURING TECHNOLOGY TRANSFER

To help fight this global public health concern, Lilly will give manufacturing firms in China, India, and South Africa the technology to convert existing facilities in those countries to produce capreomycin and cycloserine, two antibiotics used to treat MDR-TB. Facilities in China and South Africa will receive technology to produce capreomycin. Those in India and South Africa will be provided with the technology to produce cycloserine. Lilly also is currently pursuing opportunities to convert facilities in Russia for the production of these two drugs.

Purdue University will assume a significant role in the program to develop training and provide certification of sound business management and good manufacturing practices for each of the facilities receiving Lilly's drug manufacturing technology. Purdue, one of just five universities in the U.S. to blend pharmaceutical education and drug manufacturing, will also be given the manufacturing technologies that will allow it to produce cycloserine, serving as a laboratory for Purdue's international training program.

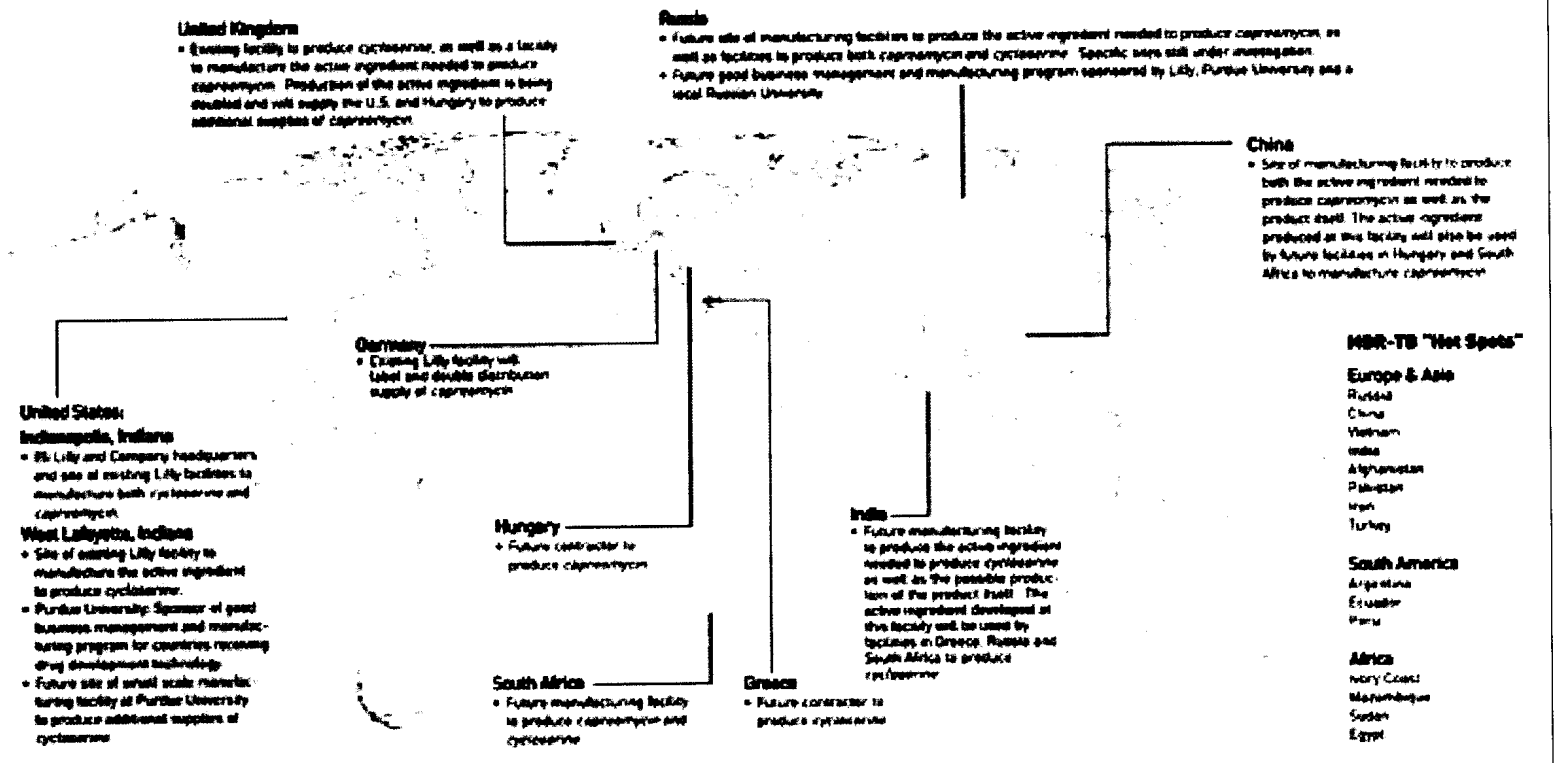
Finally, Lilly has committed to making available up to 10 full-time staff members over a 4-year period to offer technical assistance and training necessary to complete the technology transfer and ensure the long-term success of the manufacturing partnerships.

Dr. Paul Farmer, chief of the Division of Social Medicine and Health Inequalities at Brigham and Woman's Hospital and a co-founder of Partners In Health, examines a child for symptoms of MDR-TB.

PREVENTION, TREATMENT, AND MONITORING

A key component of the partnership is to conduct more research about the disease and train additional healthcare workers in the proper treatment of MDR-TB. To accomplish this goal, the Eli Lilly and Company Foundation is providing essential funding for Harvard/BWH/PIH to support a newly launched research and training initiative for MDR-TB in Tomsk, Siberia, one of the world's hot spots for this deadly public health threat. As a part of the initiative, healthcare workers from Russia and other countries of the former Soviet Union with high burdens of MDR-TB will be trained, while research data obtained will be used globally to

Transferring Technology and Increasing Drug Supply



improve and potentially develop new treatments for the disease. The first training program was successfully begun in Tomsk on November 11, 2003.

"Presently, there are too few physicians, nurses, laboratory personnel, and program managers who are both experts in MDR-TB treatment and capable of training others," said Dr. Farmer. "This initiative represents the next step in the global fight against MDR-TB, which must treat those already afflicted and prevent the emergence of further resistance. Through improved training of key health care workers and the gathering of new data, we can develop best practices based on what we've learned from our experiences at Tomsk and use them to address the epidemic in other hot spots elsewhere in Russia and the world."

Reported cases of TB, the precursor to development of MDR-TB, have more than doubled in Russia since 1990, surpassing former peaks in the 1970s. New TB infections among children in Russia have also doubled between 1986 and 1998. These dramatic increases in TB have created the potential for deadlier, drug-resistant strains of MDR-TB. In the general population of Tomsk Oblast, 13.3 percent of new TB infections are now MDR-TB. In the rest of Russia, rates range from 5 to 45 percent of new cases.

The research and training initiative will be complemented by the establishment of an MDR-TB monitoring program to track potential development of resistance against antibiotics used to treat the illness. The CDC will oversee this effort with funding provided by an educational grant from the Eli Lilly and Company Foundation to the CDC Foundation. The WHO, PIH, and leading Russian institutions will participate in this effort. Funding will be used to develop an electronic information system that will be used to connect MDR-TB treatment centers within Russia and other countries.

Lilly will also provide funding to support the International Council of Nurses in developing, jointly with other partners, guidelines and best practices for nurses in treating TB and MDR-TB. These guidelines will be disseminated for training to nursing associations around the world.

Finally, in an effort to prevent further global outbreaks of MDR-TB, Lilly and the other members of the initiative will work with governments to encourage them to adopt the WHO's protocols for treating TB and MDR-TB. The vast majority of TB cases originate in countries that have not adopted the DOTS program.

INCREASED SUPPLY AND DISCOUNTED PRICE

In addition to the increased supply created by the transfer of manufacturing technology, Lilly has made a significant investment in its Liverpool (United Kingdom) facility to double bulk production of capreomycin. The company has also negotiated manufacturing contracts with non-Lilly facilities in Hungary and Greece that will increase the supply of both antibiotics. Lilly will continue to provide both drugs at a fraction of their cost to WHO-approved MDR-TB DOTS-Plus programs around the world. The value of this discount is approximately $25 million (USD).

Additionally, Lilly is negotiating stipulations as to how much a company to whom the manufacturing technology is transferred can charge designated purchasers in emerging or developing nations for capreomycin and cycloserine. For the companies receiving this technology, a controlled partner price will provide a margin that can sustain the business while increasing the global supply of these necessary drugs.

"Lilly has been a global healthcare leader for more than 125 years. This initiative addresses a serious and growing healthcare need while establishing a model for bringing together public and private organizations for a greater good."

Sidney Taurel
Chairman, President,
and Chief Executive Officer,
Eli Lilly and Company

"This initiative is one of the few multi-dimensional efforts that involve aspects of disease prevention, treatment and surveillance, drug supply, and the sharing of formerly proprietary technology and information with foreign companies to address a growing public health threat. Lilly is to be commended for its leadership in this innovative public-private initiative."

Tommy G. Thompson
Secretary, United States Health and
Human Services and Chairman,
The Global Fund to Fight AIDS,
Tuberculosis and Malaria

For more information about the Lilly MDR-TB Partnership, visit our website at www.lillyMDR-TB.com.

Lilly
Answers That Matter.