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FEDERAL HEALTH MINISTER TONY CLEMENT URGED TO KEEP CANADA'S PROMISE TO THE DEVELOPING WORLD

Canadian HIV/AIDS Legal Network seeks streamlined law on exporting lower-cost medicines to developing countries

Toronto and Mexico City, August 5, 2008 — The Canadian HIV/AIDS Legal Network will urge federal Health Minister Tony Clement to simplify Canada's Access to Medicines Regime to allow developing countries quicker access to AIDS treatment during a meeting today at the International AIDS Conference in Mexico City. The biennial conference is attended by 25,000 delegates from around the world and Canada's Access to Medicines Regime is a hot topic, having been used just once since it was created more than four years ago.

"If the Government of Canada is serious about helping people in developing countries struggling with the AIDS pandemic and other public health problems it must amend the Access to Medicines," said Richard Elliott, Executive Director of the Canadian HIV/AIDS Legal Network. "While this one use of the law to date is great news for the patients that should soon benefit from the first shipment of medicines, there's a very real risk the Regime won't get used again unless it's streamlined."

Canada's Access to Medicines Regime was created by legislation passed unanimously in Parliament in May 2004, the *Jean Chrétien Pledge to Africa*. It is meant to allow compulsory licensing of patented medicines, so that generic drug companies in Canada can legally produce and export lower-cost versions of patented, brand-name medicines to developing countries. Canada's law is based on an agreement reached at the World Trade Organization (WTO) in 2003 that loosened WTO patent rules for this purpose.

Two months ago, Apotex, Inc., Canada's largest generic manufacturer, announced that it had successfully bid on a contract to supply the Government of Rwanda with a tablet that contains a new combination of three existing anti-retroviral drugs used in AIDS treatment. It will export the product under the first compulsory licence issued under the Regime. This represents the first (and only) use anywhere in the world of one of the handful of laws allowing compulsory licensing for exports. It is expected that the first medicines will be delivered in September.

Under Canada's current law, a generic manufacturer can only apply for a compulsory licence authorizing exports *after* tentatively lining up a contract with a purchasing country. The Legal Network criticized the process, which is based on WTO rules, as backwards, saying that what is

needed instead is a process that gives generic manufacturers more flexible legal authorization up front, so they can bid on supply contracts with many potential purchasers without being hamstrung. Furthermore, the current law requires separate negotiations with patent-holders for a separate licence for each purchasing country and each order of medicines — unnecessarily complex procedures that the Legal Network attributed largely to lobbying by brand-name pharmaceutical companies at the WTO and in Ottawa.

"When Canada hosted the last International AIDS Conference, two years ago in Toronto, the Minister acknowledged publicly that the legislation wasn't working and said he was seeking advice on how to make it work," recalled Elliott. "We've repeatedly outlined for the Minister and his advisors what the problems are, and what the solutions could be, but so far the government has refused to act."

Last year, in April 2007, the Legal Network organized an international meeting of experts in Ottawa, including developing country representatives who handle procuring medicines, to discuss Canada's Regime. The same month, the Legal Network presented the government and a Parliamentary committee with a submission containing 13 concrete amendments they could pass immediately in order to make the law truly workable. But in December of last year, the government tabled a long-overdue report in Parliament stating that it was "premature" to make any changes.

"We did their homework for them," said Elliott. "What we need is a straightforward system that is user-friendly for both developing countries and for generic manufacturers in Canada. Instead of the current process, which requires separate negotiations and a separate licence for each country and each order of medicines, we need a simple 'one-licence solution' such as the one we've proposed. Otherwise, Canada's Access to Medicines Regime could end up being a one-hit wonder."

About the Canadian HIV/AIDS Legal Network

The Canadian HIV/AIDS Legal Network (www.aidslaw.ca) promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research, legal and policy analysis, education, and community mobilization. The Legal Network is Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.

For more information on the Legal Network's proposed amendments to Canada's Access to Medicines Regime, see "Getting the Regime Right", the 2007 brief to Parliament, available at www.aidslaw.ca/gtag Publications.

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