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HEALTH AND INDUSTRY MINISTERS SHOULD ELIMINATE RED TAPE IN CANADA'S LAW ON GENERIC MEDICINES FOR EXPORT

Federal government review must be followed by immediate action

TORONTO, **November 24**, **2006** — Ottawa needs to remove unnecessary bureaucratic barriers that are preventing generic drug companies from producing and exporting affordable medicines to developing countries, the Canadian HIV/AIDS Legal Network and Médecins Sans Frontières (MSF) said today.

"Thousands of patients in developing countries aren't getting medical treatment because they can't afford brand-name medicines," said Rachel Kiddell-Monroe of Médecins Sans Frontières. "We need to get rid of the red tape standing between affordable medicines and the patients who need them."

Earlier this afternoon, federal Industry and Health ministers Maxime Bernier and Tony Clement announced the government is starting its review of the *Jean Chrétien Pledge to Africa* (also known as "Canada's Access to Medicines Regime") — a review originally announced in August by Minister Clement. This law, passed more than two and a half years ago, was intended to allow generic drug companies in Canada to produce and export much-needed lower-cost versions of brand-name drugs to developing countries. To date, however, not a single pill has left Canada.

"We've studied the law and we know what needs to be done to give it the best chance to work," said Richard Elliott of the Canadian HIV/AIDS Legal Network. "We look forward to meeting with ministers Bernier and Clement to expedite the government's review and to get to work on streamlining the law."

Currently, the law requires a company wishing to manufacture and export a generic version of a brand-name drug to apply for a separate licence for every drug order it receives.

"This drug-by-drug, case-by-case approach makes no sense. Such a convoluted and drawn-out system can never respond to the urgent needs of patients in

developing countries who are dying each day from preventable and treatable diseases," said Kiddell-Monroe. "The law should only require one licence per drug."

The Legal Network and MSF are also calling on the federal government to change the law to:

- allow any pharmaceutical product to be eligible for compulsory licensing — right now, only a limited list of products are eligible for export and the list is just extra red tape;
- disclose the name of a developing country purchasing a generic drug only after a compulsory licence is issued, with the royalty rate determined by the formula contained in the law — right now, the law is unclear about when the name can be disclosed, leaving the door open for governments or corporations opposed to compulsory licensing to put political and economic pressure on potential purchasing countries to discourage them from even seeking a generic version of a brand-name drug;
- set a maximum number of days for generic and brand-name drug companies to negotiate a voluntary licence — without a clear limit, such negotiations can drag on, preventing a generic company from getting a compulsory licence; and
- eliminate the 'expiry date' on a compulsory licence with the current two-year limit on the licence, if a developing country needs to continue buying a generic drug after the licence has expired, it must start the compulsory-licensing process from scratch.

"The drugs needed by developing countries exist," concluded Elliott, who also speaks on behalf of GTAG, the Global Treatment Action Group, a broad-based coalition of over 80 Canadian non-governmental organizations. "Let's get these drugs to the patients who need them by simplifying this law and making it easier to use — and let's do it now."

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.

About Médecins Sans Frontières

Médecins Sans Frontières / Doctors Without Borders (www.msf.ca) is an independent international medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural or manmade disasters, or exclusion from health care in more than 70 countries.

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