## Canada can set global precedent with Patent Act changes, but flaws in legislation could undermine potential benefit



TORONTO – The Canadian HIV/AIDS Legal Network welcomed today's introduction by the federal government of amendments to the Patent Act that would allow exports of lower-cost generic pharmaceutical products to developing countries. But the Legal Network also stressed that the bill is flawed as it stands, and must be improved in two key ways if it is to actually achieve the stated objective of improving access to treatment for millions of people in the developing world.

"This is an important, historic step by the Government of Canada", said Richard Elliott, Director of Legal Research & Policy. "We commend the government for responding quickly to the call to action from Canadian and international civil society and from Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa."

Elliott also congratulated the government for heeding the message that the amendment should not be limited by only allowing exports of pharmaceutical products for specific diseases or only once a country's situation had become an "emergency." But the Legal Network also cautioned that the legislation must not include provisions that undermine its potential benefit, and highlighted two major concerns.

First, "the amendment should not be limited to a list of specific pharmaceutical products," said Elliott. He pointed out that humanitarian organizations, human rights activists, and developing countries resisted all such efforts at the World Trade Organization to narrow down the options for developing countries to just a handful of medicines. "What is required is a flexible approach. It makes no sense from a public health perspective to limit the pharmaceutical products that countries could obtain from generic manufacturers. All countries – and developing countries are no exception – should be able to make sovereign decisions in determining which products are needed to respond to public health problems in their setting, without having to get further approval from the Canadian government."

Elliott also pointed to a second major concern with the bill that has been introduced. He said the legislation would be fatally flawed if it includes a so-called "right of first refusal" for brand-name drug companies, as this would effectively allow brand-name drug companies to "freeze out" generic companies from actually supplying lower-cost products to meet the public health needs of developing countries.

"The whole point of this exercise was to ensure that developing countries can effectively use the process of giving licences to generic companies in order to get lower medicine prices. If the legislation always gives the brand-name pharmaceutical company the right to take over a contract that a generic manufacturer has negotiated with a developing country, and thereby block the generic manufacturer from getting a licence to produce for export, then it removes any incentive for generic companies to even bother negotiating those contracts. As a result, we won't actually end up seeing lower prices, from

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either generic companies or brand-name companies," Elliott explained. He rejected as inaccurate the suggestion that granting a brand-name company the right of first refusal is required by WTO rules.

The Legal Network expressed its expectation that the government will be open to further discussion on these important points before the legislation in finalized and introduced by the government in the next session of Parliament.

"We look forward to further consultation with the government on these issues," said Elliott. "We fully support action to improve access to affordable medicines in developing countries, as a matter of fundamental human rights. Now we need to make sure Canada, as the first country in the world to take this step, doesn't undermine its own initiative and set a bad global precedent."

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**Advisory**: Richard Elliott, the Legal Network's Director of Legal Research & Policy, will be delivering a public presentation on the subject of the Patent Act amendment at the University of Toronto, University College (Room 240), 15 King's College Circle, later today (Thursday, November 6) from 2:00 – 3:30 p.m. The event is open to the public and to media.

The Canadian HIV/AIDS Legal Network (www.aidslaw.ca) is a national organization engaged in education, legal and ethical analysis, and policy development. Founded in 1992, the Network's promotes responses to HIV/AIDS that respect human rights; facilitate prevention efforts and access to care, treatment and support; minimize the adverse impact of HIV/AIDS on individuals and communities; and address the social and economic factors that increase vulnerability to HIV/AIDS and to human rights abuses. The Network is an NGO in Special Consultative Status with the Economic and Social Council of the United Nations. Its work has received national and international recognition, and the United Nations Joint Programme on HIV/AIDS has included the Network's activities in UNAIDS' collection of "best practices."