Hearing on Bill C-393
House of Commons: Standing Committee on Industry, Science and Technology (INDU)

Statement of Emi MacLean
Campaign for Access to Essential Medicines
Médecins Sans Frontières / Doctors without Borders
October 26, 2010

Bonjour; good morning; and thank you, honourable Committee Members.

Médecins Sans Frontières is an international medical humanitarian organization working in over 65 countries. I would like to make three primary points based on our experience. First, quite simply, medicines save lives in poor countries. Second, access to effective and affordable medicines depends on generic competition. And, third, Canada can do more than it is currently doing to support access to medicines in developing countries.

Medicine saves lives

The problem of access to medicines extends to any new drug and to all diseases. Yet AIDS continues to serve as a powerful example of both the dire needs, and also of the potential provided by price-reducing generic competition alongside political will.

MSF began to provide AIDS treatment in 2001. Myriad people said it was not possible to provide treatment in poor countries: "There was insufficient infrastructure," it was said. "Poor patients will not take their treatment regularly." Even: "Africans do not have watches; how can they know when to take their treatment?" At the time there were only 8000 people in Africa accessing treatment.

Now these arguments ring hollow. At MSF clinics, we now enroll thousands a year rather than dozens. We are innovative based on resources available: nurse-initiated treatment is common and effective; treatment is radically decentralized and simplified – away from hospitals towards health posts, under trees, on the roadside.

To the skeptics, it is working: 5.2 million people are on ART who would not be alive without it. And a 2006 study found that Africans were on average more adherent than patients in North America.

Patents matter

The treatment scale-up over the past decade has only been possible as a result of generic competition. Generic competition caused annual first-line ARV drug prices to plummet from over US$10,000 to US$67 today for the least expensive regimen.

I was in South Africa with MSF in 2002 when our goal was to provide treatment for 180 people in a pilot project. That first batch of patented drugs cost more than the car that drove the medicines from the pharmacy to the clinic.

That may be fine for a pilot project to prove the skeptics wrong and make a dent in the overwhelming need. But MSF could not provide AIDS treatment for 160,000 people, as we do today, at the price charged by brand-name manufacturers.

Nor could the Global Fund – to which the Canadian government just contributed US$520 million over three years. PEPFAR, a major procurer of AIDS drugs, has likewise acknowledged the significance of generic competition in its global AIDS contributions. Initially resistant to the use of generic medicines, PEPFAR now procures 90% of its AIDS medicines from generic manufacturers.

PEPFAR estimated that it saved US$215 million in 2008 alone through the use of generic ARVs. US$215 million. In one year, PEPFAR's cost *savings* from generic procurement is more than one year of Canada's contribution to the Global Fund. That is not to praise the United States or to denigrate Canada, but simply to show the profound significance of generic production in bringing costs down and making a scarce resource more available.

But times are changing. The dramatic reductions from generic competition are no longer available for newer medicines as a result of the TRIPS agreement intellectual property requirements. Second-line AIDS medicines, improved first-line drugs, and newer medicines for other diseases are and will be more expensive, sometimes prohibitively so. And fixed-dose combinations – three-in-one pills necessary for good adherence and rapid scale-up – cannot be created if patented by different manufacturers.

In human terms: Ten million are in immediate need of first-line AIDS treatment. Drug prices matter dearly for the people on the sidelines.

There is also an approaching "treatment timebomb," the phrase recently used by the UK Parliament's All-Party Parliamentary Group on AIDS. Increasingly patients will need to switch to newer drugs for long-term survival. But the price difference is massive between the cheapest first-line medicines, available in generic form - and improved first-line, second-line, and salvage therapy, which are not. For second-line treatment, the difference in cost is a factor of 7. For salvage therapy, at least 23 times as expensive.

Drug costs will increasingly limit patient options and swallow health budgets without dramatic price reductions.

<u>Canada can do more</u>

AIDS is only an example. And it need not be the case. Compulsory licenses provide a mechanism to allow for generic competition despite patent barriers. Compulsory licenses on efavirenz led to a 50% price drop in Thailand, and a 77% drop in Brazil, allowing the additional treatment of 20,000 in Thailand and a threefold increase in Brazil.

A workable Paragraph 6 Decision is critical for countries with no or insufficient generic manufacturing capacity, particularly as even least developed countries are obligated to adhere to TRIPS and enforce patents by 2016. In Canada's first attempt to implement the Paragraph 6 Decision, it created unnecessary additional barriers for these most disadvantaged countries needing to use the system because they lacked domestic manufacturing capacity. Why should the poorest countries be triply burdened?

MSF invested years, ultimately unsuccessfully, trying to use the system. There was clear need. But the burdens on countries and generic manufacturers were so substantial, and the delay so long, that we secured a WHO-prequalified Indian generic before CAMR could be made workable. Notably, it was not a question of an inability to compete with the Indian supplier: once produced, the Apotex fixed-dose combination was US$143/ppy compared to US$176/ppy from Aurobindo/Cipla. Canada could compete on price, but Canada hobbled because of CAMR's mandated slow speed and ineffectiveness.

If someone in Ottawa or Quebec or Toronto acquires HIV, she can expect to live to about 70 years. What is available for those in developing countries living with HIV? We urge Canada to support the easiest possible access to affordable medicines in developing countries with insufficient generic manufacturing capacity. The industry will always have excuses. But will the government?