GLOBAL HEALTH

New free trade agreement could make generic drugs less accessible in the Americas

Guillermo Murillo of Costa Rica held up his bottle of generic AIDS medications. "I come here as a person living with AIDS who is alive today thanks to these medicines," he told negotiators at the Free Trade Agreement of the Americas (FTAA) Miami meeting in November 2003.

"I want to say that I do not think the countries represented here today have the right to include themes related to medicines in trade agreements because they have failed to complete their obligations to protect the health of their people."

It was a rare instance where FTAA negotiators heard directly from a citizen. Murillo's impassioned plea appeared to have a powerful effect on some lead negotiators, said Cailin Morrison, a Vancouver-based legal advisor to Médecins Sans Frontière's Access to Essential Medicines campaign.

Still, Costa Rica, along with all the nations of Central and South America and the Caribbean (except Cuba) — encompassing some 800 million people in all — will likely find its timely access to affordable, essential medicines stymied by provisions of trade agreements signed with the US.

MSF and other nongovernmental organizations such as Health Gap, the Consumer Project on Technology, and Human Rights Watch have been raising the alarm about FTAA negotiations and US trade negotiations with subgroups of those countries.

At issue is the fact that the US is putting enormous pressure on these countries to accept levels of intellectual property protection that are much more restrictive than those currently required by the World Trade Organization (WTO).

In essence, the US is doing an end run around those WTO agreements, which now give countries the right to take measures to protect public health and promote access to medicines, notes Michel Lotrowska, spokesperson for MSF in Brazil. These WTO agreements are the refinements to the Trade Related Aspects of Intellectual Property Rights (the so-called TRIPS agreement) as articulated in the Doha Declaration on TRIPS and public health. These affirmed the rights of countries to take measures such as compulsory licensing to override drug patents when necessary to protect public health. (Compulsory licensing allows countries to override patents and produce or import generic drugs, with reasonable payments to the patent holder.)

The US agreed to the Doha Declaration, and yet the provisions of the latest FTAA draft give 5 years of data exclusivity to patent holders. This means that for 5 years, data used for the registration of medicines could not be relied upon by third parties, for example for registration of a genetic product. This would effectively tie the hands of signatory countries, delaying for as many years the introduction of even off-patent generic drugs and limiting a country's ability to use compulsory licensing to produce or import generic versions of patented drugs, according to an analysis by MSF.

The same data exclusivity provision is in the recently released final text of the Central American Free Trade Agreement (CAFTA), an agreement between the US and a subset of the FTAA countries, including Guatemala, Honduras, Nicaragua, El Salvador and Murillo's home country, Costa Rica.

To Antonio Girona, MSF's head of mission for AIDS treatment in Guatemala, this restriction is appalling. "People with HIV/AIDS in Central America do not have 5 years or more to

Brian Atkinson, MSF-CA

The Americas may lose access to generic medicines, leaving thousands, such as this Haitian mother and daughter who suffer from AIDS, without drugs.

DOI:10.1053/cmaj.1040308

wait for affordable AIDS drugs to become available."

Other provisions in the latest FTAA draft would extend patent terms beyond the TRIPS agreement and put limits on compulsory licensing "in direct contradiction" of the Doha Declaration, according to an analysis by the Consumer Project on Technology. Collectively, these provisions are referred to as "TRIPS plus."

The media office of the United States Trade Representatives did not return numerous telephone requests for comment.

"We've been going around to the FTAA countries, meeting with ministers of health and trade, talking about the dangers of [reduced] access to medicines and urging countries not to trade away health," said Morrison. But, in the end, the pressure on the countries has been enormous and many have buckled under, she noted.

The progress of the FTAA has been rocky — talks broke down at the latest meeting in Pueblo, Mexico in early February — but in the meantime, the US has been busy negotiating with subgroups like CAFTA and completing bilateral agreements, as with Chile.

A proposal at the Puebla meeting to enshrine the Doha Declaration into the FTAA was unsuccessful, noted Lotrowska. "Opposition is growing, but at the moment it looks like when it is 2005, the whole world will be TRIPS plus."

Morrison said MSF has been urging the FTAA countries to implement the Doha Declaration into national law and to use its provisions. Such a measure would at least "sit in uncomfortable" relation to any stricter proposals and act as a tool to pressure the United States.

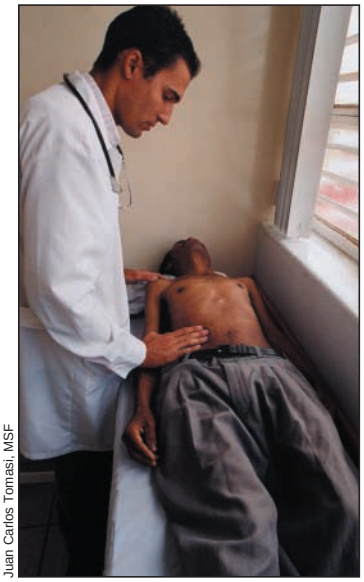
In FTAA negotiations, Canada's official position has been that intellectual property provisions should not go beyond WTO agreements, a government official said. — *Ann Silversides*, Toronto

GENERIC MEDICINES

FTAA could interfere with proposed Canadian patent legislation allowing generic exports

DOI:10.1053/cmaj.1040309

The Free Trade Agreement of the Americas (FTAA) threatens to weaken or even render useless Canada's proposed federal legislation to allow the export of generic versions of patented drugs to the developing world, says Richard Elliott of the Canadian HIV/AIDS legal network.



Juan Carlos Tomasi, MSF

Vision of the past? Guatemalan physician Alberto de Dias examines a patient to see if he qualifies for ARV treatment.

Draft provisions in the FTAA would put major roadblocks in the way of the countries of South and Central America and the Caribbean seeking to import lifesaving generic drugs from Canada or elsewhere, he noted.

For example, requirements that signatories agree to 5 years of data exclusivity would seriously delay access to needed medicines. Data exclusivity means that the information used to register medicine can not be relied upon by third parties, for example for registeration of a generic product.

Similar restrictive provisions have already been enshrined in the bilateral trade agreement between the United States and Chile, and are in the final text of the Central America Free Trade Agreement.

"There are quite serious implications for Canada in these agreements," Elliott said. And if Canada were to sign an FTAA that included such restrictions, the [proposed] Canadian legislation would be "eviscerated," he told *CMAJ*.

Canada's initiative, embodied in Bill C-56, followed an August 2003 World Trade Organization General Council agreement to facilitate the Doha Declaration by making it easier for countries to import generic versions of patented drugs if they lack domestic drug manufacturing facilities.

"It would certainly give a symbolic boost if Canada refused to sign an FTAA" because of restrictive intellectual property provisions, said Elliott, whose group has been closely involved with the formation of the domestic legislation. "But I am not holding my breath."

However, a Canadian official engaged with the FTAA's intellectual property negotiations, who requested anonymity, expressed certainty that "we would see to it not to sign an agreement preventing us from what we are doing at the domestic level ... quite frankly how could we on one hand pass legislation allowing us to do something and then sign an agreement" making this impossible? — *Ann Silversides*, Toronto