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Dear Mr. Clark and Ms. Zirger

The following submission provides comments and feedback on how Canada's Access to Medicines Regime can better achieve its objectives of improving access to affordable, urgently needed medicines in developing countries. The majority of our comments are based upon a University of Toronto-Connaught Grant research project entitled "*Improving Drug Access through Compulsory Licensing: Canada's Role?*" The project is examining whether CAMR is likely to achieve its humanitarian objectives and the potential barriers encountered by developing countries under this law.

Please do not hesitate to contact me for questions or clarifications.

Sincerely,

Jillian Clare Cohen

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Assistant Professor

Policy Gaps in the Canadian Access to Medicines Regime

A Submission to Industry Canada and Health Canada

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Background

This submission provides comments on how Canada's Access to Medicines Regime can better deliver on Canada's commitment to improve access to affordable, urgently needed medicines in developing countries.

Pharmaceuticals are indispensable to health outcomes; they can complement other types of health care services to reduce morbidity and mortality rates and enhance quality of life. However, about one third of the global population does not have regular access to medicines or no access at all. Following the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement on Public Health, Canada set an international precedent by passing legislation to allow for the export of generic drugs to developing countries facing public health emergencies and without the requisite manufacturing capacity to undertake a compulsory license domestically.

Despite the good intentions behind the legislation, not one pill has crossed the border to help improve access to medicines globally. A secured, sustainable route for access to medicines is needed and in the current form, Canada's Access to Medicines Regime is unworkable. The legislative review of the current government is promising however, unless significant policy flaws are addressed, the Canada's intentions to help improve global drug access will not result in any gains, only international shame.

Policy Concerns

Below we summarize some of our concerns which are mostly based on a University of Toronto-Connaught Grant research project titled "*Improving Drug Access Through Compulsory Licensing: Canada's Role?*" This research project is examining whether Canada's Access to Medicines Regime (CAMR) is likely to achieve its humanitarian goals, and the potential barriers encountered by developing countries applying for compulsory licenses under this law. The project's primary data are open-ended interviews to stakeholders directly involved in the drafting, negotiation and implementation of CAMR, as well as individuals with a high political interest in its outcome. Participants interviewed include representatives of developing countries, generic and research-based pharmaceutical companies, members of international organizations regulating health and trade, non-governmental organizations , as well as Canadian government officials. Where possible, we present our findings according to the topics identified in the submission request. However, we go beyond these issues.

Eligible Products

One of the most glaring deficiencies in the current crafting of the legislation is that it does not reflect global pharmaceutical market conditions. The vast majority of cheap, generic drugs are being exported to least developing countries from sourcing countries such as India, China and Brazil. The current drug list does not reflect many of the drug needs of developing countries simply because many are already sourcing these products elsewhere. For example, in Africa, drugs are needed for malaria and second and third-generation anti-retroviral drug therapies.

From a price-point, Canadian producers are unable to compete given input costs are significantly lower in these countries. So the legislation should be structured to take into account what is Canada's comparative advantage in terms of pharmaceutical production capabilities. The legislation ought to focus more strategically on drug products that these countries are not able to produce given existing intellectual property requirements. It also fails to sufficiently reflect drugs which are in the pipeline.

It is not realistic to assume that countries will break existing contractual agreements to make use of the Canadian legislation. Simply from the point of view of administrative costs, it is not in a country's best interest to change existing agreements. These and other deficiencies could have been easily addressed had there been sufficient input from developing country representatives - the intended beneficiaries of this legislation in the first place. Developing country representatives ought to be informing Canada of what their drug needs are. These needs will obviously vary depending on patent regimes in place, epidemiological profiles of a given country and budget capacity.

The fundamental model for Schedule 1 was the WHO Essential Medicines List, which many are beginning to challenge. Cost-effectiveness is a key factor in determining whether or not a drug is on the list. Eleven of the 14 patented products on the current list are antiretroviral drugs, while the remaining three are for other diseases (tuberculosis, malaria, trypanosomiasis).[1] The legislation must not ignore the necessity for drugs to treat non-communicable diseases, which were responsible for 59% of global deaths in 2002 and estimated to increase to 69% by 2030.[2] Some products on the list address these conditions, however many of them are already available in generic form from other source countries. Developing countries need the flexibility in the legislation to determine their specific drug needs.

Recommendation

Remove the list of eligible products and allow importing countries to determine their own drug needs. Removal of the list may provide economic incentive to generic companies as it would open up the possibility of developing their capacity for drugs that will be off patent in the near future.

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[1] http://www.cptech.org/blogs/ipdisputesinmedicine/2006/12/letter-asking-who-review-of-essential.html

[2] Mathers CD, Loncar D (2006) Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med 3(11): e442. doi:10.1371/journal.pmed.0030442

Application Process

A major hurdle in the effectiveness of this legislation is the onerous requirements pursuant to the application process. The need for preliminary voluntary license negotiation between the generic company and the multiple patent holders is a lengthy, complex and expensive process, as clearly illustrated through the MSF-Apotex case. This obstacle suggests that the legislation is not designed to achieve its objective – addressing urgent public health crises. What is more, if a voluntary license is not granted, it is unlikely that generic companies will pursue a compulsory license given that the costs of this, primarily legal costs, would be high with little benefit in return.

Recommendation
Amend the legislation so that a compulsory license is granted without prior negotiations.

Duration of the License

The two year compulsory license is a clear disincentive for generic companies. The process leading up to the compulsory license is time consuming and subject to expensive legal fees, which the generic company will unlikely pursue given the absence of economic benefits and the fact that they need to remain competitive. This is particularly the case if a company would need to adjust and/or increase their manufacturing infrastructure for products which are not normally part of their product portfolio.

Recommendation
Remove the limit on the duration of the compulsory license.

The Good Faith Clause

One of the primary sources of tension inherent to this legislation is the need to ensure both humanitarian and commercial interests are addressed. In its current form, the legislation fails to provide satisfactory inclusions on both accounts. The legislation must provide better commercial incentives in order to meet its policy objectives. The provision that demands explicit recognition of non-commercial objectives should be removed. It is not good policy to demand that the generic industry morph into a non-profit agency when applying this legislation. What the government ought to be crafting into this legislation are clear commercial incentives for the generic companies so they will want to compete for business pursuant to this law. Philanthropy, while morally appealing, will not make this legislation work and help get drugs to those who desperately need them for quality of life or life itself.

Recommendation
Remove provisions requiring explicit recognition of non-commercial objectives including the limits and liability on product price.

Quantities Exported Under License

The limit on the quantity permitted for the license is a disincentive for both non-governmental organizations and developing countries. In some cases, the capacity to assess specific drug quantities may be daunting.

Recommendation
Lift the limits on authorized quantity and allow commissioner to assess on a case-by-case basis, keeping in mind that a country's drug needs are dynamic.

Anti-Diversion Measures

The pharmaceutical industry has emphasized that one of their concerns about this legislation is the risk of drug diversion. However, to date, there has been very little evidence to suggest that this is a common problem.[3] What is more, there are procedures which can be used to help ensure that diversion risks are mitigated. In 2003, the European Commission passed a Council Regulation (EC)953/2003 to prevent reimportation of differentially priced products into EU member markets.[4] These types of initiatives may lessen industry's concerns about diversion of pharmaceutical products produced under this regime.

Closing Points

Commercial Needs

Generic companies are commercially oriented and need to have the right incentives to undertake humanitarian goals. Amendments to provide more incentives could include tax breaks for generic companies that use the legislation. Another disincentive is the competitive disadvantage that Canadian generic manufacturers have against developing countries such as India, China, and Brazil. Canadian producers are highly unlikely to be more price competitive unless specific subsidies or tax credits are provided to them under this legislation. Finally, the application process is timely, expensive and ultimately not worthwhile for generic companies if there is no guarantee of a demand or a sufficient return on investment in the process.

Developing Country Health Needs

The legislation imposes a "one-size" fits all approach to medicines. Developing country drug needs should be considered on a case-by-case basis so that its particular barriers vis a vis patents, regulation, capacity are taken into account. The beneficiaries of the legislation must be included in the planning and delivery process.

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[3] Outterson K: Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets. Yale Journal of Health Policy, Law and Ethics 2005., 5(1).
[4] http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl

In crisis situations, government officials will not opt to deal with cumbersome administration in order to get drugs to those in need. A country with a death toll from AIDS does not have the time or resources to engage in these complex procedures for every single drug. The legislation wrongly assumes that developing country governments have the requisite know-how, and human resource capacity to make use of it.

We can better assist developing countries by being more imaginative with our manufacturing capabilities (e.g. help countries develop their own technical capacity or initiate joint-ventures with developing country firms) and the existing network of NGOs.

Canada's Role

Canada's Access to Medicines Regime tries to remedy a market failure while still relying on market mechanisms to achieve its goals. Commercial objectives are critical to making this work because they help attain the affordable prices and large volumes through economies of scale and competition. Humanitarian initiatives will not solve the problem.

Canada must assume a more effective role globally in the drug access area by taking on a role as a mediator, bring parties together, being more proactive on both a bureaucratic and political level to make this work. For example, the government could support and mediate collaboration between the generic and research-based companies, proactively identify potential importing countries, engage private foundations like the Clinton Foundation and NGOs.

Canada needs policy coherence to make this work. As first step, it should honor its commitment to provide 0.7% of the GNP allocated to Official Development Aid, Canada's position at trade negotiations must be consistent with its commitments under the TRIPS Agreement to respect the right of countries to implement TRIPS flexibilities to address its public health concerns. Canada could provide drugs as aid to countries or tie it to existing international grants. Finally, while Canada increased its contributions to the Global Fund, it has the capacity to do more to finance the procurement of affordable, life-saving drugs.

For clarifications or questions please contact:

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