Making Canada's Access to Medicines Regime Work for Countries in Need: A Case Study on Ghana

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The AIDS in Africa Working Group and the Access to Drugs Initiative: University of Toronto, Faculty of Law, International Human Rights Program

Canada's Access to Medicines Regime

In May 2004, Canada was the first country in the world[1] to implement the WTO General Council's August 30th 2003 decision, which allows for the compulsory licensing of essential medicines for export to countries in need. Despite the prompt enactment of the legislation, no country has, as of yet, indicated any intention of trying to use Canada's Access to Medicines Regime (CAMR). It has become increasingly obvious that if any medicine is to be exported through the CAMR system, there has to be a major revision to its provisions.

Purpose of this Report

The Access to Drugs Initiative (ADI), with the support of the Faculty of Law's AIDS in Africa Working Group, and CIDA has fostered a relationship with the Government of Ghana to examine the possibility of procuring Canadian generic pharmaceuticals through the CAMR system and to provide recommendations for improving the Ghanaian 2003 *Patent Act*. Armed with this unique practical experience, knowledge, and perspectives of the concrete challenges facing Ghana, ADI and the AIDS in Africa Working Group has identified a number of ways in which the CAMR could and must be improved to make it a feasible and useful option for countries in need.

Assessing the CAMR from this perspective is instructive for a number of reasons. From the outset of the ADI/Ghana collaboration, Ghanaian officials were keenly interested in accessing medicines through the CAMR. Specifically, Ghana was looking to see how Canada might assist Ghana in providing affordable treatment for the thousands of Ghanaians living with HIV/AIDS.[2] Ghana's interest in the CAMR was matched by ability—Ghana has a well-structured government, strong administrative support, and TRIPS-compliant legislation, all essential elements in the sustainable procurement and distribution of essential medicines. Significantly, Ghana has demonstrated its willingness to use compulsory licensing, a strategy which has elsewhere faced intractable political resistance. In 2005, Ghana became the first country in West Africa to actually issue a compulsory license.[3] This compulsory license was issued for public health purposes to import four HIV/AIDS medicines from India.[4] If a country like Ghana, with the political will to issue compulsory licenses and the administrative infrastructure to do so is unable to make use of the CAMR, there is minimal chance that other developing countries without such strong advantages can benefit from the regime.

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[1] Other countries that have since implemented the decision include Norway, China, India, the European Union, Korea, Switzerland, and the Netherlands. "Canada's Access to Medicines Regime – Consultation Paper" *Canada's Access to Medicines Regime* (24 November 2006), online: Review of Canada's Access to Medicines Regime <http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_tab1_e.html> [CAMR Review]

[2] "Summary Country Profile for Treatment Scale-Up," *World Health Organization* (June 2005), online: "3 by 5" country profile on treatment scale up, June 2005 [pdf 422kb] <"3 by 5" country profile on treatment scale up, June 2005 [pdf 422kb]>

[3] See Courage Quashigah, "Notification of Emergency and Issuance of Government Use License," (26 October 2005), online: Compulsory License Copy of original <http://www.cptech.org/ip/health/cl/Ghana.png>

[4] This compulsory license did not engage the August 30th 2003 decision as these medicines were not under patent in India.

Minister Clement has invited submissions to the review of the legislation that is currently underway and due to be reported before May 2007.[5] This report is one such contribution, and assesses the CAMR's usefulness to the developing countries and men, women and children living with HIV/AIDS, malaria, and TB whom this legislation was pledged to help.

As the recommendations that follow will explain, there are a number of problems with the existing CAMR regime that are impacting the ability of the legislation to deliver upon its promises. Amongst other things:

(i) CAMR does not take into the account the realities of international drug procurement regimes (i.e. a public tendering process), and thereby increases the gulf between manufacturers of drug products and the international funding required to pay for medicines.

(ii) CAMR is unnecessarily restrictive in its limiting of the scope of eligible drugs and importers, and decreases the appeal of obtaining a license to a generic manufacturer by imposing onerous technical and legal requirements, limiting the license term to two years and creating a complicated and costly process for renewing licenses.

(iii) CAMR fails to leverage the full potential allowed under not only the August 30th decision, but also its own drug approval capacity, thus undermining Canada's intent to support and promote increased access to affordable medicines.

While the difficulties inherent in the August 30th decision itself may, in fact, be challenging to overcome, the following recommendations nonetheless must be implemented to ensure that Canada is well positioned to make the greatest possible impact on the HIV/AIDS pandemic.

Recommendations

1. **Recommendation:** Repeal 21.04(2)(f), which requires a generic producer applying for a license to specify the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product will be sold.

When selecting an international supplier, Ghanaian procurement authorities are required by law to issue an international call for tenders and then select the best tender based on objective criteria, foremost of which is price. These laws prevent its government from approaching Canadian companies directly or engaging in any negotiations outside the tendering process. Only once the Canadian tender is accepted will Ghana and the Canadian producer be on track to forming an agreement. Ghana's procurement procedure is an internationally standard procurement method.

[5] S. 21.2(1) and 21.2(2) of 2004, c. 23 (Bill C-9) [hereafter CAMR]

The CAMR, however, seems to envision a system in which potential importing countries bear the onus of contacting pharmaceutical companies in Canada. According to the CAMR website, "*Once an arrangement has been established*, the responsibility for submitting an application under the Regime belongs to the..."[6] But if the parties need to be on track to forming an agreement before even applying for a license, Canadian companies would have to submit tenders before they have a license, in other words, before they can even assure importing countries that they can follow through on their offer.

Section 21(1)(a)(i) of *Ghana's Public Procurement Act* 2003 reads: "A tenderer in public procurement shall possess the necessary professional and technical qualifications and competence."[7] Depending on how this Act is interpreted, Canadian companies may not meet these "technical qualifications" due to their lack of a compulsory license at the time of their bid.

Even if Ghana's laws do not categorically prevent Canadian companies from bidding on tenders, Canadian bids will be less appealing because of their uncertainty, not only as to whether a license will be granted, but also on what terms. Attempts to integrate consideration of this uncertainty into the tender selection process will be difficult and introduce subjectivity into a process that was designed "to establish efficient, transparent and accountable procurement procedures."[8] In the long run, generic producers will have to raise prices, in order to factor in the cost of breaching those contracts they were not able to deliver upon. The Canadian companies that do include this additional cost will not only make less profit on their investments, they will also have less competitive bids. Companies from other countries which are not saddled with the CAMR legislation are not hampered by this cost. Hence, if all operating expenses are equal, the foreign manufacturer will submit a lower price.

From the perspective of the importing country, the consequences are much more dire than commercial inviability. If Ghanaians living with HIV/AIDS who are on antiretroviral[9] (ARV) therapy are suddenly denied access to ARV medicines because of a supply failure, they risk developing resistance to their treatment regime. The result is that they would then need to be moved to another, more expensive treatment regime which may very well be unavailable within the country.

The CAMR should be designed to cater to standard international procurement methods, which are considered to be more objective, transparent, and efficient than direct negotiation. The WTO's Interagency Guidelines, accepted by the Global Fund,[10] agree that procurement "should be based on competitive procurement methods," as opposed to "direct negotiation," as envisioned by the CAMR.[11] They recommend that "formal written procedures should be developed and followed throughout the tender, and explicit criteria should be used to make

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[6] Emphasis added, "Finding a Drug Company," *Canada's Access to Medicines Regime*, (28 July 2006), online: Finding a Drug Company <http://camr-rcam.hc-sc.gc.ca/countr-pays/import/compan-entrepris_e.html>

[7] *Ghana's Public Procurement Act* 2003, Section 21(1)(a)(i).

[8] "Ghana: Strengthening Government Procurement," *Doha Development Agenda: Trade Capacity Building Database*, World Trade Organization, online: WTO TRTA & CB <http://tcbdb.wto.org/trta_project.asp?prjcd=ur-00043/01&ctry=47>

[9] An antiretroviral is a substance that suppresses the activity of a retrovirus, for example, HIV.

[10] "Guide to the Global Fund's Policies on Procurement and Supply Management," *The Global Fund* (November 2006), online: pp_guidelines_procurement_supplymanagement_en.pdf <http://www.theglobalfund.org/pdf/guidelines/pp_guidelines_procurement_supplymanagement_en.pdf> [hereafter Global Fund Procurement]

[11] WTO Interagency guidelines: http://hinfo198.tempdomainname.com/medicinedocs/collect/edmweb/pdf/whozip49e/whozip49e.pdf

procurement decisions." This type of formal procedure is reflected in Ghana's procurement process. This objective process decreases corruption because it eliminates incentives for politicians to choose companies willing to offer perks to high level decision-makers. Ghanaian procurement authorities also simply do not have the resources to seek out individual generic manufacturers across the globe and to educate themselves on each country's pharmaceutical laws and regulations.

While the August 30th decision itself requires that the importing country notify the WTO before a Canadian company can apply a compulsory license, the August 30th decision does not prevent a Canadian company from first applying for a compulsory license and then responding to a call for tenders.

One provision of the CAMR that is unnecessary in order to comply with the August 30th decision and that inhibits a Canadian company from applying for a license before responding to a call for tenders is section 21.04(2)(f) of the CAMR. This section requires a license applicant to specify "the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity." Two separately problematic parts of this provision are the requirements (1) to specify the name of the person or entity to which the product is sold and (2) to sell only to a governmental entity and to seek the permission of the importing country.

(1) Problem: Specifying the identity of the person or entity to which the product is to be sold

Ascertaining this specific information adds unnecessary time and complication to the process and damages the robustness of the license; if the specified person or entity changes once an agreement is actually formed, the license itself may possibly be invalidated.

(2) Problem: Selling only to a governmental entity or to an entity that has been "permitted" by the government of the importing country

The CAMR system, which envisions a bilateral agreement between a Canadian generic producer and a developing country government, does not reflect the realities of pharmaceutical procurement in its envisioned importing countries. In particular, the system fails to fully accommodate the tremendously important role of NGOs and international procurement agencies in procurement of affordable pharmaceuticals. Ghana, for instance, procures many of its pharmaceuticals from the International Dispensary Association, a not-for-profit organization that specializes in the provision of high-quality, low-cost medicines and medical supplies to developing countries.

Going beyond the stipulations of the August 30th decision, the CAMR requires procurement entities (PE) to have the permission of importing country governments before accessing the CAMR system. As the Canadian HIV/AIDS Legal Network rightly points out, this requirement complicates the process and subjects NGOs to political pressures.[12]

[12] Interagency Pharmaceutical Coordination Group, "Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement," World Health Organization (Geneva: WHO, 1999). WHO/EDM/PAR/99.5 online: whozip49e.pdf http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip49e/whozip49e.pdf

Nor does this requirement offer redeeming benefits if the described right-of-intervention is included. Potential PE's must work closely with importing countries in order to ensure proper notification to Canada or the WTO, to implement any anti-diversionary measures (as per Article 4 of the August 30th decision), and to issue any compulsory licenses. Importing countries that have carried out these activities likely already approve of the PE intending to access the CAMR or have alternate plans which could readily be cited in the PE's license application. In any case, s. 21.1 of the CAMR explicitly mentions CAMR compulsory licenses are non-exclusive. The real obstacle faced by the CAMR is not having enough parties interested in the CAMR, not too many. Any steps that can be taken to promote reputable PE involvement in the CAMR should be encouraged.

The CAMR should not require that a NGO seeking to procure pharmaceuticals for the benefit of an importing country seek the permission of that importing country. Instead, importing countries should be notified by the Government of Canada of any application to the CAMR system made on their behalf. If the situation ever arises that (1) a NGO is able and actively seeking to access the CAMR system on behalf of an importing country and (2) that importing country government objects to these actions, the importing country government could challenge this application with its own application to the CAMR or with notification of its intentions to apply to the CAMR.

Section 21.04(2)(f) should be repealed, and the rest of the revised legislation reviewed for procedures that would inhibit engaging in a competitive procurement process.

(3) Additional problems

Canada also needs to revise the guidelines on its website to make it clear that the following sequence is possible: (1) an importing country notifies the WTO of its lack of manufacturing capacity and required pharmaceutical. (2) A Canadian company responds by applying for a compulsory license. (3) Once that authorization is acquired, the company responds to a Ghanaian call for tenders by submitting a realistic and accurate tender. (4) If the company's tender is accepted, the two parties then consummate their agreement.

It is absolutely essential that all participants in the CAMR system are reassured that their actions are legitimate, legal, and, as much as possible, safeguarded against litigation. This is especially true given that participants will face (or at the very least fear they will face) resistance and potentially economic pressure not to use the system.

A common complaint about the CAMR is that it only allows for a fixed quantity of exported pharmaceuticals and only allows this quantity to come from one specified supplier.[13] In the particular case of Ghana, however, these hurdles do not seem to be a major problem. Similar to other developing countries and many international procurement agencies, Ghana has a limited international bidding process under which qualified drug companies[14] submit a tender and the

[13] See e.g. Richard Elliott, "Pledges and Pitfalls: Canada's legislation on compulsory licensing" (2006). Vol. 1 Nos. 1/2 Int J. Intellectual Property Management 103, online: Canadian HIV/AIDS Legal Action Network <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=725> [hereafter Pledges and Pitfalls] and Médecins Sans Frontières, "Neither Expeditious, Nor a Solution: The WTO August 30 Decision is Unworkable" (Paper presented to the XVI International AIDS Conference, August 2006) 6, online: <www.msf.ca/aids2006/files/REP_JCPA_en.pdf> [hereafter Neither Expeditious Nor a Solution]

[14] For example, Ghana often requires the bidders to have WHO pre-qualification since such pre-qualification is needed to access Global Funds.

highest bidder is awarded the contract.[15] The tendering process usually specifies the exact type and quantity of medication needed from a supplier. Therefore, the fixed quantity and specific supplier restrictions of the CAMR would be consistent with Ghanaian procurement procedures and would not impose undue hardship, *as long as the licensing process itself is fast, cost-effective, and certain enough to allow tendering companies to fully participate in the competitive procurement process.* It is important to recognize, however, that this report focuses on the Ghanaian experience with the CAMR. The problems that these restrictions do pose in other countries are left to other commentators to address.

2. **Recommendation:** Eligible pharmaceuticals should not be limited to the list in Schedule 1.

Schedule 1 of the CAMR lists 56 pharmaceuticals that can be exported using the CAMR. Many of the medicines currently appearing on the list are not the products that a country like Ghana would be most interested in procuring from Canada. Ghana is particularly interested in procuring second-line ARV treatment pharmaceuticals. As the country is not currently procuring any second- line treatment, Ghanaians who are fortunate enough to afford second-line treatment must travel outside of the country for treatment.

While the CAMR does incorporate a process to amend the list of eligible medicines, this process takes time and creates additional cost and uncertainty in a way that exacerbates the already problematic interaction of the envisioned CAMR system with standard government tendering and procurement laws in developing countries,. It is a given that pharmaceutical needs will evolve and evolve quickly over time; fixing the list invites political battle time and time again. For the one medicine that has been added to the list of eligible medicines, oseltamivir phosphate, it took over four months to even publish the proposed amendment for public comment.[16]

Nor is it realistic or sustainable to believe that non-governmental organizations, international procurement organizations, Canadian generic producers, or other advocacy groups would be able to solve this problem. In practice, the only two additions to the schedule made so far have been instigated by a Canadian generic producer in collaboration with the NGO community.[17] However, these organizations will not have the same kind of incentives, resources, nor the specific knowledge that an importing country government charged with the health of its nation would have access to.

No other country with equivalent legislation has handicapped its own effectiveness by imposing such a limited list.[18]

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[15] See "Procurement of Goods: International Competitive Tendering," *Public Procurement Board*, Republic of Ghana (October 2003), online: Standard Tender Document – Procurement of Goods – International Competitive Tendering (ICT) <http://www.ppbghana.org/tenders/biddingdocs.asp>

[16] Joanne Csete, "Re: Addition of oseltamivir phosphate to Schedule 1 to the *Patent Act*," Letter from Canadian HIV/AIDS Legal Network to Industry Canada (26 July 2006), online: Letter to Susan Bincoletto, Director General of Industry Canada's Marketplace Framework Policy Branch <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=706>

[17] CAMR Review, *supra* note 1,

[18] CAMR Review, *supra* note 1, Annex B, online: camr-rcam <http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_tab1_e.html> [hereafter CAMR Review comparative annex]

3. **Recommendation:** Implement a license renewal process that is fast and easy, and increase license duration.

Like many other countries dealing with the AIDS pandemic, Ghana experiences difficulties in forecasting its drug needs, resulting in empty-shelf emergencies. This is a very serious problem for countries in need of ARV drugs since treatment interruption can result in the development of resistance to the medication, and possible central nervous system injuries.[19]

The hurdles that exist in obtaining a compulsory license, however, make it extremely challenging for Canadian companies to respond to Ghanaian emergency drug needs. An approval from Health Canada takes 7 months, WHO pre-qualification takes an additional month, and on top of that there is also required negotiation with the patent holder(s).[20] Based on the current hurdles within the CAMR, Canadian generic manufacturers are in no position to respond to these emergency needs.

If the provision that licenses expire within two years is to be retained at all, then it is critical that a speedy license renewal process be in place whereby existing compulsory license holders can extend or re-apply for licenses in a timely manner, without the need for re-approval from Health Canada and negotiation with the patent holder. This is distinct from the "Renewal" provision of s. 21.12 of the CAMR, which is essentially only an extension of time in which to fulfill the exportation already authorized under a previous license.

Although this renewal process cannot resolve emergency needs for generic drugs that Canadian companies do not already supply or have supplied under compulsory license, this process will at least allow manufactures, who have the capacity to respond to the emergency, to do so without being prevented by a lengthy licensing process.

Related to the issue of license renewal is the issue of license duration, which currently stands at two years (s. 21.09). A look at the ARV procurement contracts awarded by UNICEF shows that on average, an ARV contract lasts twelve to twenty-four months.[21] Another reference point is the six to nine months ARV procurement contracts awarded by WHO.[22] The length of these contracts are not, however, indicative of the optimal length for a compulsory license. The durations of the contracts cited above are more easily, and with more certainty, renewable. As well, these organizations benefit from the economies of scale of supplying a large number of countries on an ongoing basis.

Compulsory licenses need to last longer than two years. While a specified time limit does offer more certainty and predictability than a more discretionary determination of license length,

[19] Gisslen M, Rosengren L, Hagberg L, et al "Cerebrospinal fluid signs of neuronal damage after antiretroviral treatment interruption in HIV-1 infection." *AIDS Res Ther.* 2005 Aug 18;2(1):6, online: http://www.aidsrestherapy.com/content/pdf/1742-6405-2-6.pdf

[20] Although the CAMR specifies that patent holders and the generic manufacturer have up to one month to reach an agreement, the negotiation between Apotex and the triple-dose ARV patent holder have taken much longer than that. It is not clear what was stalling this negotiation process.

[21] This website lists all contracts awarded by UNICEF, categorized by month and year. "Procuring supplies for children," UNICEF, online: UNICEF – Procuring supplies for children – Contract Awards <http://www.unicef.org/supply/index_27009.html>

[22] "ARV Procurement By Principal ARV Procurement By Principal [sic] Recipient Under GF Funding," *Bi-regional workshop on the management of antiretroviral medicines: Phnom Penh, Cambodia*, AIDS Medicines and Diagnostics Service (AMDS), World Health Organization (13-16 December 2004), online: khm17.pdf <http://www.who.int/hiv/amds/capacity/khm17.pdf>

[23] the current two-year limit imposes too short a time frame for surmounting the considerable obstacles to obtaining a compulsory license. It hampers the ability of generic manufacturers to achieve economies of scale, which may hurt the viability of their enterprises and throw into question the long-term sustainability of supplies.[24]

4. **Recommendation:** Explicitly permit use of the regional exportation exception described in Article 6 of the August 30th decision. Amend s. 21.05(2), 21.04(2), and 21.14 so that an applicant who intends to make use of the regional exportation exception can be authorized to produce pharmaceuticals for the eligible regional trading agreement.

Article 6 of the August 30th decision permits countries who have imported pharmaceutical products under the August 30th decision provisions to re-export those products to other countries in the same regional trade agreement (RTA), provided that the RTA qualifies as a RTA under GATT and half of its members are least-developed countries. This section is a specific acknowledgement of the fact that countries with little or no manufacturing capacity will likely not have the kind of market size to interest pharmaceutical manufacturers or to benefit from bulk purchasing. In the long-term, this exception also allows members of these RTAs to circumvent the formidable legislative and administrative barriers that prevent them from accessing the August 30th decision individually, and benefit from the other advantages of bulk purchasing.

The Economic Community of West African States, of which Ghana is a member, is eligible under this exception, and the Ghanaian government has expressed interest in exploring the possibility of becoming a regional importer to the benefit of all ECOWAS countries. Regional procurement without compulsory licensing has already been demonstrated to yield substantial price reductions and other benefits to, for example, the Organization of Eastern Caribbean States and the Gulf Cooperative Council.[25]

Currently, this regional exportation exception is implicitly recognized by s. 21.14(f), which provides that a license may be terminated if: "(f) the product exported to the country or WTO Member…has been…re-exported *in a manner that is contrary to the General Council Decision*." S. 21.14(f) implies, therefore, that the re-exportation allowed by the regional exportation exception is not a recognized ground for license termination. At the same time, the CAMR detracts from the potential usefulness of the regional exportation exception by limiting

[23] In India, for example, the Controller General of Patents is at liberty to determine the terms and conditions of the license, and no limitations are placed as to the duration of this license. In the Netherlands, the duration of the license is similarly discretionary.

[24] Canadian HIV/AIDS Legal Network and Interagency Coalition on AIDS and Development, "The Jean Chrétien Pledge to Africa Act and its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries" (1 August 2006), online: Publications – Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=583>

[25] The Organization of Eastern Caribbean States succeeded in reducing prices on procured pharmaceuticals by an average of 44 percent. The Gulf Cooperative Council by 30 percent. See Centre for Pharmaceutical Management, "Regional Pooled Procurement of Drugs: Evaluation of Programs," Submitted to the Rockefeller Foundation. 2002 (Arlington, VA: Management Sciences for Health)

the quantity of licensed pharmaceuticals to only the quantity needed by the importing country (s. 21.05(2)).[26]

In order to promote certainty and predictability in the operation of the legislation, this important August 30th TRIPS exception should be made explicit in the CAMR. Specifically, s. 21.05(2) and s. 21.04(2) should be amended. The authorized quantity should be allowed to exceed the quantity needed by the importing country if the applicant (1) states that it or its partner intends to use the regional exportation exception and (2) specifies what quantities of pharmaceuticals are reasonably needed by the importing country and any other countries in the eligible regional trading area it specifies it would like to supply, and justifies its figures. If any of these regional trading partners has already notified the WTO or the Government of Canada of the quantity of its pharmaceutical need, the applicant should cite that figure instead of deriving its own. S. 21.14 could be amended so that the patent-holder can appeal to have the license limited to just the quantity needed for the eligible importing country if either of the following conditions are met: the patent-holder demonstrates that the quantity of the product exported from the importing country to eligible regional trading partners exceeds the quantity, if any, authorized for that regional trading partner, or the patent-holder demonstrates that, within the knowledge of the applicant, the quantity consumed in the importing country exceeds its specified need.

The proposed provisions seek to accommodate the three models for regional importation that the CAMR should allow: (1) the importing country government could negotiate with the applicant for pharmaceuticals and then independently arrange to export these to regional trading partners. (2) RTA member states could collaborate from the start to import pharmaceuticals through one country for redistribution to the RTA partners (3) The applicant or other entities could seek to import the pharmaceuticals into the importing country and participate in distributing them throughout the RTA.

The proposed provisions also avoid requiring regional trading partners to notify the WTO or the Government of Canada of their required quantities of pharmaceuticals, something which is not required by the August 30th decision. The fact that no country has yet made any notification to the WTO reflects how daunting even the act of notification can be, in light of educational shortfalls, resource constraints, and political resistance.

5. **Recommendation:** Repeal s. 21.17 altogether, which deals with allowable prices for the pharmaceuticals.

S. 21.17 of the CAMR holds that if a generic producer sells a pharmaceutical for more than 25 per cent of the Canadian list price and this exceeds their manufacturing costs plus 15 per cent, then the patent-holder may call for a review.[27] If the above conditions are met, the patent-holder may apply to the court for an order terminating the compulsory license or ordering a higher royalty on the basis that the generic's contract is "commercial" in nature as opposed to "humanitarian." S. 21.17 invites litigation and discourages generic producers from even engaging in the CAMR system.

[26] S. 21.05(2) specifically limits the quantity authorized for production to the *lesser* of the maximum stated by the applicant in his application and the quantity set out in the importing country's notice.

[27] Saul Chernos, "Canada: Activists Claim Partial Victory on Export of Generic Drugs," *Inter Press Service* (5 May 2004)

There are a number of reasons why this privilege does not make sense: (1) The manufacturing costs exception does not take into account factors like the cost of developing a high-quality generic equivalent to the patented version and the legal risk of using the CAMR system. (2) From the perspective of an importing country with urgent need for affordable pharmaceuticals, it is of course better to have access to pharmaceuticals that are inexpensive than not to have access to those pharmaceuticals at all, which is what would likely happen if a license is revoked. A more effective and practical way to keep down the prices of essential pharmaceuticals is to allow competition and promote efficient manufacturing practices, not the opposite. (3) Repealing this section will not cause harm to the patent-holder. The pharmaceutical at issue will often not be available in the developing country at any price, meaning the patent-holder has nothing to lose by allowing generic producers to export to that country. Even considering the possible case where a patent-holder *is* supplying pharmaceuticals to a privileged few in the importing country who can afford it, the argument is unconvincing: the fact that the CAMR system allows for generic producers to supply pharmaceuticals at less than 25 per cent of the average cost at all means that as soon as a generic producer satisfies the rigours of the CAMR system, it would be able to dominate the market anyway. The existing CAMR system already accepts and allows this to happen. One sign that this provision is excessively onerous and ineffective is that no other country has imposed a similar restriction.[28]

6. **Recommendation:** Streamline and expedite the Health Canada approval process. Ideally, the fast-track approval process for CAMR pharmaceuticals should take four months.

The CAMR requires that pharmaceuticals that are to be produced under compulsory license for export are approved by Health Canada.[29] As such, Health Canada has created an expedited approval process for such medicines,[30] which took, in the case of Médecins Sans Frontières's (MSF) application for a drug manufactured by Apotex, approximately seven months.[31] At the same time, that many developing countries and donor organizations require imported medicines to be prequalified by the World Health Organization (WHO) as well, resulting in a double-prequalification.[32] WHO prequalification normally takes a minimum of three months, [33] although if Health Canada approval has been granted, the *additional* WHO pre-qualification process has been reduced in length to as little as about one month.[34] That means that, currently, if the Health Canada approval requirement of the CAMR were removed as MSF

[28] CAMR Review comparative annex, *supra* note 21.
[29] *Food and drug regulations*, S.O.R./ 2005-141.
[30] Pledges and Pitfalls, *supra* note 14
[31] Neither Expeditious Nor a Solution, *supra* note 14.
[32] *Ibid*.
[33] "About the Prequalification Programme," World Health Organization (3 January 2007), online: Prequalification Programme <http://mednet3.who.int/prequal/default.htm> (Under "About") ("The prequalification process takes a minimum of three months if the product meets all the required standards.")
[34] MSF applied for WHO prequalification for the manufacture of 3FDC by Apotex in December 2005 and approval was granted in July 2006: Rachel Kiddel-Monroe from Médecins Sans Frontières, '"Will it deliver?" WTO rules and Canada´s law on compulsory licensing - the continuing challenge of scaling up treatment access" (Lecture presented to the XVI International AIDS Conference, August 2006), English audio file online: <http://www.aids2006.org/PAG/PSession.aspx?s=918>.

recommends, then the total pre-qualification process would be reduced from eight months (seven months for Health Canada approval and one month for WHO pre-qualification) to four (four months for WHO pre-qualification). Neither national regulatory approval nor WHO prequalification are, after all, required by the August 30th decision.

However, in practice, taking such action may frustrate the goals of the CAMR by making its use less appealing to African nations. Canadian legislation and regulations need to be cognizant of what kind of role or niche Canadian generic producers are best-suited to fill – namely high quality, technically complex pharmaceuticals. Ghana, for example, has indicated that the Health Canada approval feature was one of the motivating factors prompting them to consider accessing medicines under the Canadian regime.[35] For years, Ghana has been importing AIDS drugs from India, which has a relatively unregulated scheme that permits unimpeded export. However, in recent years, there have been several incidents whereby medicines imported from India were removed from the shelves in Ghana due to quality concerns.[36] The population, media and government in Ghana are particularly sensitive to the issue of drug quality and regulatory approval. A clear illustration of this widespread concern can be found in the media criticism and protest march by angry citizens following an emergency purchase of drugs by the Ghanaian government from local manufacturer DanAdams, which has not yet received WHO prequalification.[37] Ghanaian officials have thus suggested that, cost being equal, drugs from Canada may look more attractive than similar products from India due to their perception that Western regulatory approval signifies higher quality medicines.

In light of Ghanaian perceptions, it seems that Health Canada approval adds something of value to the CAMR which could, in some circumstances, give it a competitive advantage over other August 30th decision regimes not requiring similar approval, such as in the Netherlands. It is likely that quality concerns and similar perceptions will draw other African nations to the CAMR due to its Health Canada approval provision. Eliminating the Health Canada approval requirement could potentially thus jeopardize a valuable component of the CAMR. Equally important, eliminating the requirement might create the perception that Canada thinks it appropriate to create a double standard in drug quality, with less rigorous requirements imposed on drugs exported to Africa than on drugs consumed by its citizens. As such, the benefits of maintaining Health Canada approval within the CAMR should be closely examined before this requirement is removed from the legislation. Potential importing countries should also be consulted in order to determine how important the Health Canada approval process would be to their drug purchasing decisions. If the Health Canada approval provision is retained, the process should be immediately and continually reviewed to identify respects in which it can be made more efficient and better able to facilitate expedient access to medicines. If the Health Canada approval process could be shortened to three months, then the total time it would take to pre-qualify CAMR-licensed pharmaceuticals by Health Canada and the WHO would be just as short as the time it would take to pre-qualify those pharmaceuticals by the WHO alone.

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[35] Interview of Government of Ghana by Access to Drugs Initiative (March 2006).

[36] "Beware of Inferior Drugs," *Ghana Web News* (10 October 2006), online: Ghana Web <http://www.ghanaweb.com/GhanaHomePage/NewsArchive/artikel.php?ID=111916>; "Indian Firm Fails to Replace Dud Drugs," *Ghana Web News* (13 September 2002), online: Ghana Web <http://www.ghanaweb.com/GhanaHomePage/NewsArchive/artikel.php?ID=27353>.

[37] "A tenderer in public procurement shall possess the necessary professional and technical qualifications and competence." *Ghana's Public Procurement Act* 2003, Section 21(1)(a)(i)

7. **Recommendation:** Recognize approval from equally stringent foreign regulatory authorities, in particular the United States.

One downfall of the Health Canada approval requirement is that it might deter pharmaceutical manufacturers from exporting medicines under the CAMR. For a manufacturer that has already obtained approval from equally stringent regulatory authorities, the prospect of having to undergo an additional approval process is unappealing. In addition to being time-consuming, seeking multiple approvals is costly as legal fees and application fees are involved in each. It would therefore be worthwhile for the Canadian government to examine the costs and benefits of recognizing approvals from select foreign domestic regulatory authorities as equivalent to Health Canada approval, notwithstanding the benefits of Health Canada approval discussed above. In particular, the government should consider recognizing pharmaceuticals which have already been approved by the United States' Food and Drug Administration (FDA), which will be the issue most likely to arise in practice. The Global Fund to Fight AIDS, Tuberculosis and Malaria has deemed a number of countries to have stringent regulatory authorities,[38] approval from which qualifies a drug to be purchased with grant money from the Fund. In the longer term, Canada might also consider evaluating whether these regulatory authorities' approval processes are comparable to that of Health Canada.

8. **Recommendation:** Implement August 30th decision exceptions regarding negotiation with the patent holder.

Article 31(b) of TRIPS states that a product under a patent cannot be used without the consent of the patent holder, unless "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."[39] However, the agreement does provide one exception to this requirement, in that where there is a situation of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use," or in cases of remedying the patentee's anti-competitive behaviour, the requirement for negotiations may be waived.[40] The Canadian legislation currently contains no such exception to negotiations comparable to that provided in TRIPS.[41] In this way, the CAMR imposes legal obligations on industry and developing nations that exceed what is required by the WTO and is more restrictive than the equivalent legislation in every other country except Korea.[42]

The requirement for those seeking a compulsory license to negotiate with the patent holder has significantly slowed down the compulsory licensing process in Canada, and is considered by

[38] The Global Fund defines stringent regulatory authorities as those participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) or the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: The Global Fund to Fight AIDS, Tuberculosis and Malaria, Global Fund Procurement, *supra* note 11

[39] *Agreement on Trade-Related Aspects of International Property Rights* Article 31 (b). [hereafter TRIPS]

[40] *Ibid.*

[41] CAMR s. 21.04 (3) (c) (i)

[42] CAMR Review comparative annex, *supra* note 21.

some to be the central problem with the legislation.[43] This is, in large part, because it is unclear at what point negotiations can be declared unsuccessful.[44] In practice, it is only when both sides agree that further negotiations will be futile that negotiations can be deemed a failure.[45] This allows patent holders drag out the negotiations. MSF, who have been involved with the sole attempt to obtain a compulsory license through the AMR, argue that "Prolonged prior negotiations severely limit the ability to use the August 30th Decision and act as a disincentive to manufacturers to participate in the process."[46]

Considering this problem and considering the purpose of the CAMR, which is to address international humanitarian purposes to address public health problems, it is clear that the CAMR should implement the exceptions-to-negotiation requirements laid out in TRIPS, namely in cases of public non-commercial use, and anti-competitive practices, national emergency, or other circumstances of extreme urgency.[47] Where the importing country can make use of these exceptions, the approval process could be substantially sped up.

There is no established, universal standard for what constitutes a national emergency or case of extreme urgency. According to article 5 (c) of the Doha Declaration:

> Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.[48]

That is, each member state has the right to decide whether HIV/AIDS constitutes a national emergency or case of extreme urgency in their country. The Doha Declaration further states that it is not necessary for a country to legally declare a national emergency, but that it is "sufficient for the national health authority to state that a compulsory license be granted because of a national emergency or extremely urgent public health circumstance."[49]

For example, the Ghanaian HIV/AIDS situation, with a rate of infection of 3.1 per cent in 2004, constitutes an epidemic according to UNAIDS/WHO standards.[50] Ghana has already issued a compulsory license, based on its consideration of the HIV/AIDS epidemic as a situation of extreme urgency.[51] If the AMR had an exception in cases of national emergency or other circumstances of extreme urgency, Ghana could very well be importing AIDS medicines from Canada. Ghana's HIV/AIDS epidemic clearly establishes a case of a national emergency or extreme urgency.

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[43] Joseph Hall, "Canada Breaks AIDS Pledge: Africa Still Waiting for Life –Saving Drugs Two Years After Ottawa Passed 'Breakthrough' Law." *The Toronto Star* (3 August, 2006), online: The Toronto Star <http://www.thestar.com/NASApp/cs/ContentServer?pagename=thestar/Layout/Article_Type1&c=Article&cid=1154556610138&cal>

[44] Neither Expeditious Nor a Solution, *supra* note 14.

[45] Lee Berthiaume, "Drug Access Seriously Flawed," *Embassy* (16 August, 2006), online: Embassy – Newspaper Online <http://www.embassymag.ca/html/index.php?display=story&full_path=/2006/august/16/access/>

[46] Neither Expeditious Nor a Solution, *supra* note 14.

[47] TRIPS Article 31(b) and (k)

[48] World Trade Organization 'Declaration on the TRIPS agreement and public health', *Ministerial Conference*, Fourth Session, Doha, 9-14 November, WT/MIN(01)/DEC2 [hereafter Doha Declaration on Public Health]

[49] The World Bank "Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies." Ed. Yolanda Taylor, 2004.

[50] Ghana AIDS Commission, "National HIV/AIDS/STI Policy," (4 January 2005), online: Ghana AIDS Commission http://www.ghanaids.gov.gh/main/results_detail.asp?story_id=116

[51] *Supra* note 4.

License applicants should be allowed to forgo the 30-day required negotiation period with patent holders in cases of public, non-commercial use, anti-competitive practices, national emergencies, or other circumstances of extreme urgency. An importing country should be able to simply declare that it is suffering a "national emergency or other circumstances of extreme urgency" to qualify under this exception. Almost all countries that have implemented the August 30th decision that have stipulated any requirement at all to seek a voluntary license have included this exception for emergency situations.[52]

There are other measures that should be taken to expedite the process of trying to negotiate a voluntary license. The CAMR should include a maximum period beyond which negotiations with patent-holders can be declared failed. The "reasonable terms and conditions" for potential voluntary licenses should be described to some extent. However, the specifics of these recommendations are left to parties with more direct, Canadian, supply-side experience.

9. **Recommendation:** Amend s. 21.14, the circumstances in which a patent-holder can apply to terminate a license, to make the license less brittle.

S. 21.14 states that "[o]n the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the authorization if the patentee establishes…" any of an enumerated list of things. This should be reworded to authorize the Federal Court to give discretionary remedies proportionate to the breach of the CAMR identified. Termination of the license should be avoided where the contested pharmaceutical product is addressing a health emergency in the importing country.

Absurd scenarios should be avoided. For example, the breach in s. 21.14(a) is if "the application contained any material information that *is* inaccurate." After sufficient use of the license, a patent-holder could theoretically quibble, therefore, that because the quantity needed by the importing country, which was submitted as part of the application, has changed, the application contains material information that is *now* inaccurate.

Conclusion: An opportunity to lead the world in improving access to medicine.

At the outset of any re-evaluation of the CAMR, it should be acknowledged that even legislation that takes advantage of *all* the flexibilities offered in the August 30th decision will still not necessarily be accessible to those who need it most. A handful of countries have now implemented the decision, yet no eligible importing country has yet stepped forward and notified the WTO and the world of its need and desire to engage the system. Not surprisingly, the importing countries that lack manufacturing capacity and face the kinds of public health crises

[52] Countries that have implemented a national-emergency exception to negotiations for a voluntary license are Switzerland, Norway, the EU, CAMR Review comparative annex *supra* note 21, and, despite its not being mentioned in the latter hyperlinked appendix, the Netherlands, s.57(1) of the Dutch Patents Act 1995, see online: http://www.cptech.org/ip/health/cl/netherlands-export-rules.html)

this legislation was designed to address also lack the educational, technical, and legal resources to engage this new, untested system. Many also lack the political will to withstand the political and economic backlash that may follow a fulsome engagement of the system, particularly if countries such as Canada fail to fully support and uphold the right of all countries to access lifesaving medicine.

Nevertheless, there are a host of improvements that could be made to the CAMR to maximize the possibility of its being useful, both to Ghana and to others. At the heart of the CAMR's problems lies a disconnect with the realities of pharmaceutical procurement methods and needs in eligible importing countries. The August 30th decision was designed to aid the many, diverse, often small countries that lack manufacturing capacity and that face serious public health problems. In order to do this, the CAMR must be consistent with standard procurement methods; it must stipulate concrete criteria which pharmaceutical companies can satisfy and predictably be awarded licenses; and it must allow for adaptive, flexible, creative, and quick public health responses. Canada was the first in the world to implement the August 30th decision; if sufficiently overhauled, it could also be the first in the world to actually use it

We would also be remiss to fail to note that Canada's commitment to Africa ought not to be strictly limited to promoting access to drugs through an enabling legislative regime. Canada is well-positioned to support other initiatives that will improve overall access to medicine and treatment of disease. For example, Canada is well-positioned to support the harmonization of drug approval regimes in Africa. Canada has a well-respected drug approval system and is bilingual. Harmonization of drug approval would have a major impact on improving drug distribution systems in the region, and facilitating market penetration for generic drug manufacturers. Canada could also play a greater role in promoting investment and research into neglected diseases through a combination of domestic push mechanisms, such as tax credits and regulatory incentives.

As a nation, we can build a bridge between the developed and developing worlds within the global free-trade regime, acting as a legitimate arbiter between the competing interests of innovation and access, developed and developing worlds, human rights and free trade. Becoming an international leader and paving the way to solving the broader problems of access to medicine in Africa is an opportunity that Canada should seize upon.

The Access to Drugs Initiative
The Access to Drugs Initiative is a coalition of faculties at the University of Toronto, lawyers, business executives, and students. We work to analyze existing methods of delivering low-cost pharmaceuticals to

states and people in need and to develop new strategies to improve developing countries' access to essential medicines.

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