Canada's Access to Medicines Regime (CAMR) Consultation
Submission by
The Human Rights Working Group on HIV/AIDS and Public Health
Faculty of Law, McGill University

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Executive Summary

Canada's Access to Medicines Regime (CAMR) is designed to facilitate access to pharmaceutical products in developed and least-developed countries by allowing generic manufacturers to produce such products under compulsory licence – but the legislation is not working. Since CAMR's passage in 2004, not one drug has left Canada, while over 25 million people have died worldwide for lack of access to existing medicines and vaccines. This humanitarian crisis requires urgent Parliamentary action to reform CAMR.

The central goals of reform should be: the removal of disincentives for generic pharmaceutical manufacturers to become involved with CAMR-related production, an increased flexibility in the terms of compulsory licensing, and streamlining the process for issuing a compulsory licence.

Specifically, **Parliament should**:

- **delete** provisions differentiating between those importing countries that are WTO members and those that are not, and correspondingly strike ss. 21.14(i)
- **eliminate** the requirement that NGOs receive "permission" from importing countries before applying for a compulsory licence
- **replace** Schedule 1 with the WTO's definition of "pharmaceutical product"
- **remove** the requirement that an importing country provide a certified copy of its notification
- **support** the development of effective domestic anti-diversionary measures
- **undertake** stricter monitoring of Canadian imports to prevent diversion
- **render optional** a Health Canada review of generically manufactured pharmaceuticals where World Health Organization (WHO) pre-qualifications have already been satisfied
- **clearly define** the "reasonable terms" required in pre-licence negotiations
- **institute** an expeditious dispute resolution process, possibly modeled after the United States' Declaratory Judgements Act
- **clarify** the national emergency waiver to allow all applicants to make use of it in cases of national emergency or other circumstances of extreme urgency in an importing country
- **replace** the two-year term limit on compulsory licences with a term that runs the remaining length of the patent
- **substitute** an internal structure like that of Regulation 816/2006 of the European Parliament in place of CAMR's litigation-prone sections
- **allow** generic manufacturers to amend the quantity and destination of pharmaceuticals produced when an importing country declares that its needs are not being met, and correspondingly strike ss. 21.14(h)
- **amend** ss. 21.14(f)-(g) to protect generic manufacturers from litigation caused by third-party error

Canada deserves credit for being the first to draft such legislation. However, Parliament must act soon to address the legislation's flaws. Only meaningful reform of CAMR can give substance to Canada's "pledge" to the developing world.

INTRODUCTION

Canada's Access to Medicines Regime (CAMR) is not working. Since it was passed in May 2004, CAMR has not resulted in the export of a single pharmaceutical product. In that same time period, according to estimates of the World Health Organization (WHO), over 25 million people have died because they could not access existing medicines and vaccines. CAMR was created "to give effect to Canada's [...] pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries."[1] The humanitarian crisis that prompted this pledge must be borne in mind throughout the review of CAMR.

In 2003, with 42 million people living with HIV/AIDS in the world,[2] the Department of Foreign Affairs and International Trade (DFAIT) Sub-Committee on Human Rights and International Development presented a report recommending that the Canadian government facilitate access to medicines in developing and least-developed countries.[3] That report was made pursuant to an Order of October 2002 to prepare recommendations for solutions to address the crisis situation in sub-Saharan Africa, which the Order characterized as an "urgent matter of humanitarian catastrophe."[4]

The catastrophe is worsening. Last year, 4.3 million people were newly infected with HIV and 2.9 million people died of AIDS.[5] Time is of the essence: developing and least-developed countries need access to essential pharmaceutical products as soon as possible. The process whereby that access is granted via CAMR must be a speedy one.

CAMR received all party support when passed in parliament[6] and every group involved in the creation and review of CAMR has a stated commitment to making it work. Although the various stakeholder groups that collaborated in its development had conflicting views on the framing of the legislation, there is broad-based support for CAMR and a general recognition of its necessity. Mr. Jean-François Leprince (President, Aventis Pharma, Canada's Research-Based Pharmaceutical Companies) affirmed the "continued support" of research-based pharmaceutical companies to the development of what he called a "crucial piece of legislation."[7] He stated:

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[1] *Patent Act*, R.S.C. 1985, c. P-4, s. 21.09, as am. by *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa),* R.S.C. 2004, c. 23, Summary [*Patent Act*].
[2] *Ibid*.
[3] *Eighth Report of the Standing Committee on Foreign Affairs and International Trade*, Part II (Ottawa: Standing Committee on Foreign Affairs and International Trade: 2003), s. 1.4, note 16.
[4] *Ibid*., Introduction.
[5] *AIDS Epidemic Update: December 2006*, UNAIDS/WHO, 2006, UNAIDS/06.29E at 1, online: <http://www.who.int/hiv/mediacentre/2006_EpiUpdate_en.pdf> [*AIDS Epidemic Update*].
[6] Health Canada, *Canada's Access to Medicine's Regime – Consultation Paper*, s. 3.0, online: <http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_e.html> [*Consultation Paper*].
[7] Standing Committee on Industry, Science and Technology, *Evidence*, 37th Parl. 3d sess., No. 004 (26 February 2004).

> "We believe that there is an opportunity for the world pharmaceutical industry, generic and brand name alike, to set aside their traditional rivalries. Both industries have a unique opportunity to be part of the solution and to focus on patient needs. We believe we must focus our efforts on finding solutions."[8]

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association) declared that "the Canadian Generic Pharmaceutical Association is strongly supportive of the government's desire to make Canadian generic pharmaceuticals available for export to developing countries".[9]

The overwhelming, undisputed exigency of the crisis means that this legislation must meet its goals. The process of accessing pharmaceutical products via CAMR must be enabled through the removal of roadblocks and flaws currently inherent in the legislation. Thus, the aim of minimizing administrative delays and complications should inform the review process throughout.

ELIGIBLE IMPORTERS

CAMR's specifications on eligible importers follow the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Decision of the General Council of 30 August 2003 defines an "eligible importing Member" for compulsory licensing as any developing or least-developed member country that has notified the WTO of its intent to take advantage of the waiver. The WTO specified that a member can notify the WTO at any time that it will use the system in whole or in a limited way.[10] Canada has implemented the WTO waiver in a manner that enables both members and non-members to import pharmaceutical products under compulsory licence. Under 21.04(2)(f) of the *Patent Act*, NGOs and other entities may also participate in CAMR by purchasing pharmaceutical products with the permission of an eligible importing country.

The inclusion of non-WTO members sets an important precedent creating legislation based on the August 30 decision. However, Canada's legislation contains different standards for members and non-members, resulting in a double standard. Non-members must prove that they are in a state of emergency to take advantage of CAMR's licensing program. This is not a WTO requirement. It creates an unnecessary additional demand upon non-member countries. Differential rules for WTO members and non-members only increase the difficulty of providing drugs to those who need them. These differential requirements should be eliminated.

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[8] *Ibid*.

[9] *Ibid*.

[10] WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003)*, WTO Doc. WT/L/450 (1 September 2003), art. 1(b), cited in *Consultation Paper*, *supra* note 6.

The "permitted by" section of the legislation provides guidelines on the permissibility of the activities of NGOs and other entities. The ability of these groups to procure and distribute pharmaceutical products is crucial to successfully dealing with the HIV/AIDS pandemic and public health crises in general. Many NGOs and similar groups are doing critical work that relies on access to pharmaceutical products. Thus they should be able to use CAMR to support this work without the additional requirement to receive "permission" from individual governments. The legislation should be amended to eliminate this requirement.

ELIGIBLE PHARMACEUTICAL PRODUCTS

Schedule 1 of the legislation provides a list of products (modeled after the WHO's Model List of Essential Medicines) that are eligible for export. Including Schedule 1 creates a bureaucratic hurdle that was deemed unnecessary in WTO discussions. Canada itself consented to excluding product lists like Schedule 1 in the August 30th Agreement. By including such a list now, Canada is unecessarily contradicting its earlier position.

HIV/AIDS treatments are constantly evolving. Under the current CAMR rules, things like newly developed drugs, new drug combinations, and new dosages require an amendment to Schedule 1. When Médecins Sans Frontières (MSF) tried to amend Schedule 1 to include a new drug, the delay lasted seven months.[11] Furthermore, the amendment process offers pharmaceutical companies the opportunity to contest changes to the Schedule, creating potentially devastating delays for the intended recipients of the pharmaceutical products.

The inclusion of Schedule 1 permits the Canadian government to decide which medicines are necessary for public health in developing countries. There is no legal or policy reason for the Canadian government to play this gatekeeper role. Decisions about which drugs are needed to fight public health epidemcis are best made by entities such as public health organizations, the governments of affected countries, and NGOs working on the ground. Schedule 1 inhibits access to pharmaceutical products. It should be eliminated.

NOTIFICATION

CAMR requires a certified copy of the importing country's notification. Certified copies are not necessary for WTO compliance. They create an additional bureaucratic hurdle. The requirement should be eliminated.

The inclusion of anti-diversionary measures in the legislation is a WTO requirement, and is thus appropriate. The prospect of back-flow of products from importing countries to developed countries, including Canada, is a potentially valid concern. Effective anti-diversionary measures require resources. Such measures would be optimized by strong cross-border cooperation. The Canadian government should

[11] "Neither Expeditious, Nor a Solution" (2006) at 7, online: Médécins Sans Frontières <www.msf.ca/aids2006/files/REP_JCPA_en.pdf> [MSF, "Neither Expeditious, Nor a Solution"].

support the development of such an initiative, and continue strict monitoring of imports into Canada to prevent diversion.

Health Canada's Drug Review

CAMR stipulates that generic pharmaceutical products must meet the requirements of the *Food and Drugs Act* and receive Health Canada Approval. MSF finds "the inclusion of this requirement in [CAMR] surprising given that Canada's regulatory regime does not require that non-[CAMR] drugs that are manufactured 'for export only' meet [these] safety, quality, and efficacy standards."[12] Health Canada review is an unnecessary step, as the medicines are already subject to review under WHO regulations, and many developing countries and donor agencies already require WHO pre-qualification of imported pharmaceutical products. The Health Canada review is a superfluous addition to this established process. As noted previously, the review has been shown to cause a seven month delay in a drug order by MSF.[13]

In cases where WHO pre-qualification has already been satisfied, Health Canada review should be optional. An optional review would increase the speed with which importing countries would receive the pharmaceutical products, and increase the number of Canadian manufacturers willing to export them.

Application Process

Under CAMR, a manufacturer seeking a compulsory licence has a prior duty to seek a voluntary licence from the patent holder on "reasonable terms." This stipulation must be clarified to eliminate disagreement over the interpretation of "reasonable terms". The 30-day minimum requirement encourages parties to enter into potentially fruitful negotiations. However, these negotiations should be informed by clear standards as to what constitutes "reasonable terms".

Without clear standards, the patent holder has the power to delay the negotiation process, which will deter generic manufacturers from participating in CAMR. Furthermore, the threat of litigation may force generic companies to choose between launching a product with the risk of being sued, or foregoing the production of pharmaceuticals under CAMR altogether.[14] This climate of uncertainty is a serious disincentive for companies to enter into and remain in the generics market.

In recognition of this problem, a recent US Supreme Court decision[15] upheld the use of declaratory judgments by generic drug manufacturers. This would provide an expeditious dispute resolution process by allowing a party to receive definitive

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[12] *Ibid*.
[13] *Ibid*.
[14] *GPhA Praises Supreme Court Decision Allowing Swifter Resolution of Patent Disputes: Court Upholds Declaratory Judgments* (9 January 2007), online: Generic Pharmaceutical Association <http://www.gphaonline.org/AM/Template.cfm?Section=Media&ContentID=3126>.
[15] *MedImmune v. Genentech*, No. 05-608, slip op. (U.S. Jan. 9, 2007).

judicial resolution of potential legal claims. In order to resolve disputes that will inevitably arise under CAMR, and to diminish the climate of uncertainty currently faced by generics companies, CAMR should include recourse to an expedited dispute resolution process such as declaratory judgments.

The Consultation Paper's statement that the negotiation requirement can be waived where an importing country faces a national emergency or other such crisis is also ambiguous. The stipulation does not specify who can declare a national emergency or crisis. According to the Consultation Paper, "some have construed this to mean that the requirement can be waived in the exporting country when there is a national emergency or extreme urgency in the importing country." This broader interpretation is preferable; in any case, without clarification this statement is open to potentially lengthy and litigation. CAMR should indicate that all potential applicants, including exporting countries, NGOs, and the importing country itself, may employ the waiver in cases where the recipient country is in a state of national emergency or extreme urgency.

DURATION OF A LICENCE

TRIPS requires that, where a generic manufacturer is granted use of a patent through a compulsory licence, "the scope and duration of such use shall be limited to the purpose for which it was authorized".[16] However, given that the "purpose" of issuing compulsory licences is a long-term concern, Canada's decision to limit their "duration" to two years[17] was neither necessary nor appropriate.[18]

Supporters of a two-year term argue that contractual parties should not be "locked in" to long-term contracts.[19] However, developing countries or other purchasers are best placed to assess and project needs, thus permitting the parties to set for themselves what they believe to be an appropriate term.[20]

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[16] *Agreement Establishing the World Trade Organization*, Annex 1C, art. 31(c), online: World Trade Organization <http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs>.
[17] *Patent Act*, *supra*, note 1, s. 1. The "scope" of compulsory licences is addressed elsewhere in this submission.
[18] Canadian Generic Pharmaceutical Association, Media Release, "Bill C-9, *The Jean Chrétien Pledge to Africa*" (2006), online: <http://www.canadiangenerics.ca/en/issues/billc-9.shtml> [CGPA, "Bill C-9"]. As noted in the *Consultation Paper*, *supra* note 6, similar legislation in the EU, Switzerland, and Korea does not prescribe a time limit for compulsory licences: European Union, *Regulation (EC) No 816/2006 of the European Parliament and the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, art. 10 (compulsory licences can only be terminated if licence conditions are not respected or if the circumstances leading to the licence no longer exist: see also Geoff Blackie, "Breathing Life into the August 30th Agreement" (2005) at 18, online: University of Toronto Faculty of Law Access to Drugs Initiative <http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20geoffblackie%20trips.doc>); Switzerland, *Draft Amendment to Federal Law on Patents for Inventions*, art. 40e.2; Korea, *Korean Patent Act as revised by Industry and Energy Committee in the National Assembly and effective as of December 1, 2005*, art. 111.
[19] Richard Elliott, "Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export" (2006) 1 *Int. J. Intellectual Property Management* 94 at 107 [Elliott, "Pledges and Pitfalls"].
[20] In addition, if protection from unfairly long contracts were truly Canada's concern, it would restrict all pharmaceutical contracts to two years – and not solely those issued under CAMR: *Ibid*.

The two-year term prevents generic manufacturers from exploiting economies of scale that can translate into lower drug costs for countries in need. This inability "throw[s] into question for potential developing-country purchasers the long-term sustainability of supplies."[21] Crucially, the two-year terms also discourage generic manufacturers from participating in CAMR by making such participation "completely uneconomic".[22] By the time a manufacturer has produced the relevant pharmaceuticals, created fixed-dose combinations, and acquired Health Canada approval, the remaining time in their patent term will not allow them to recoup their investment.[23]

The possibility of a one-time renewal[24] does not mitigate this disincentive because the renewal only extends the time-frame for delivering the quantity agreed in the original (two-year) contract. Further production in response to changing conditions must be negotiated in new contracts.[25] Thus, although the current renewal process is not unduly arduous,[26] and permits the full contracted quantity of drugs to be exported, it would better serve the interests of developing countries and the aim of CAMR to rethink the very concept of term limits so as to render a renewal process unnecessary.

The two-year term limit should thus be abandoned. Instead, the compulsory licence should run the remaining length of the relevant patent. The generic manufacturers would thus be given an incentive to participate in CAMR (with patent-holders' rights still protected through royalty schemes and restrictions on manufacturers' profits), while enabling developing countries and other purchasers to manage their public health needs.

GOOD FAITH CLAUSE

The August 30th Decision declared that compulsory licenses can be granted when used "in good faith to protect public health."[27] CAMR supplements this requirement by including numerous sections to deter generic pharmaceutical companies from producing pharmaceutical products in "bad faith" (eg. excessive profits or pharmaceutical products being diverted to other countries).[28] CAMR leaves generic manufacturers open for litigation in three areas:

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[21] Richard Elliott, "Time to Deliver (or not): Commentary on Canada's Law on Exporting Generic Medicines" (2006), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=610>; see also Blackie, *supra* note 18 at 18.

[22] CGPA, "Bill C-9", *supra* note 18.

[23] *Ibid*.; Blackie, *supra* note 18 at 18.

[24] *Patent Act*, *supra* note 1, s. 21.12.

[25] In the meantime, patent-holders can "game the system" by undercutting the generic manufacturer's price or changing the shape of their pills to force generics to expend further efforts at rendering their own product distinct. Elliott, "Pledges and Pitfalls", *supra* note 19 at 108.

[26] The process involves a straightforward application from the generic manufacturer: *Patent Act*, *supra* note 1, s. 21.12.

[27] "Modification of WTO Rules on Protection of Pharmaceuticals" (2003) 97 A.J.I.L. 981 at 982 (JSTOR).

[28] *Patent Act*, *supra* note 1, s. 21.17.

(i) The patent holder can litigate if the transactions of the licence holder appears to be "commercial in nature" or if they appear to be profiting excessively from the production of the generic medicines.[29]
(ii) Under section 21.08(4) of the Patent Act, the patent holder can apply to the Federal Court to have their royalties increased.
(iii) The patent holder can apply to have the compulsory licence terminated in cases where there is suspicion that anti-diversion measures have not been fulfilled.[30]

These sections are simply not necessary. A similar European Parliament Regulation expressly states, in paragraph 6 of the preamble, that good faith provisions can be met while discouraging litigation against generic manufacturers.[31] Articles 10 through 17 of the regulation establish and internal legal framework to police adherence to good faith that prevents recourse to the courts.[32] The European Parliament's document shows that removal of the litigation sections is possible. Canada should adopt similar measures in CAMR.

QUANTITIES EXPORTED

As part of the notification requirements, the WTO waiver requires an eligible importing country to indicate to the WTO both the name and the quantity of the pharmaceutical products it intends to import. Compulsory licences granted under the terms of the WTO waiver must be limited to this notified amount.

CAMR requires that the quantity of product authorized to be manufactured and exported not exceed the lesser of either (i) the quantity set out in the manufacturer's licence application, or (ii) the quantity indicated in the importing country's notification to the WTO or to the Government of Canada.

Limits on authorized quantities pose significant problems for importing countries. Fixed quantity restrictions cannot respond effectively to changing or growing needs for pharmaceutical products. Under CAMR, when more products than are specified in the application need to be produced and exported, a licencee must reinitiate the application process.[33] This results in significant delays in delivery of essential medicines.

Quantity limits also discourage generic manufacturers from producing essential medicines for export to developing countries. Under CAMR, generic manufacturers may obtain licences only on a product-by-product, country-by-country, and order-

[29] *Ibid*., s. 21.14.
[30] *Ibid*., s. 21.13.
[31] *Regulations (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, [2006] O.J. L 157/1.
[32] *Ibid*. Art. 10-17.
[33] MSF, "Neither Expeditious, Nor a Solution", *supra* note 11.

by-order basis.[34] Generic companies need the flexibility to produce these pharmaceutical products in larger bulk orders free from order-specific quantity restrictions in order for their investment to be viable.[35]

This rigidity in the extension process may discourage manufacturers; the costs and risks of production and regulatory approval could be greater than short-term revenues they may stand to gain under CAMR.[36] Although manufacturers may reapply if quantity needs change by the end of a contract, costs and opportunities for patent-holders to intervene in the interim are disincentives to doing so. Furthermore, such restrictions on term limits are not required by WTO rules.[37]

Licensing contracts must be flexible to adapt to changing needs. Canada should adopt a procedure that allows licencees to amend authorized quantities when the importing country's needs are not being met. Canada should also require importing countries to notify the WTO of quantity changes. It should expand and simplify the application process to allow generic manufacturers to supply in larger quantities, to more than one country per application (if necessary) to maintain the incentive to produce and export.

TERMINATION

Most of the grounds for termination are fair. However, the term "any material information that is inaccurate" needs to be clarified. There should be a distinction drawn between honest mistakes in the filing of a licence application and misrepresentations by the licensing company. Moreover, the grounds listed in 21.14 subsections (f), (g), (h), and (i) are counter to the humanitarian goals of CAMR.

Subsection (f) provides for the termination of a patent if the product is re-exported with the knowledge of the compulsory licence holder. This subsection is vaguely worded and thus invites litigation. It should be amended to specify that the license holder must have "clear and direct" knowledge of re-exportation and be in a position to prevent re-exportation. If the subsection is left as is, "knowledge" might be construed in ways that significantly increase the likelihood of termination. For instance, a termination case could currently be launched against a licence holder that was aware that part of its shipment had gone missing, although it had no power to stop the diversion.

The current wording of subsection (g) raises the same concerns and calls for the same solution: the specification of the type of knowledge the licensing company

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[34] "The Jean Chrétien Pledge to Africa Act and Its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries" (2006), online: Canadian HIV/AIDS Legal Network <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=696> [Canadian HIV/AIDS Legal Network, "The Jean Chrétien Pledge to Africa Act"].

[35] *Ibid*.

[36] Elliott, "Pledges and Pitfalls", *supra* note 19 at 107.

[37] Canadian HIV/AIDS Legal Network, "The Jean Chrétien Pledge to Africa Act", *supra* note 34.

must have and the addition of words exonerating a licensing company where the exportation was done by a party beyond their control.

The current wording of subsections (h) and (i) raises different concerns. Subsection (h) currently allows for the termination of a licence when a product is exported in a quantity greater than the quantity authorized. This may be fair if no additional royalties are paid and if the licensing company has acted in bad faith. However, the issue is better resolved by mandating additional royalty payments when a greater quantity is exported. Since the stated goal of the CAMR is to allow developing countries to address their significant public health problems, surely the exportation of a greater quantity than is initially authorized lies within the spirit of the program. Striking subsection 21.14 (h) from the legislation would create greater flexibility and shift focus towards public health needs.

Similarly, subsection (i) is unduly restrictive and runs contrary to the humanitarian goals of the program. As has been addressed elsewhere, "commercial purposes" is a vague statement that should be modified or removed from the legislation altogether. In the countries covered by subsection (i), public infrastructures may not allow for the effective dissemination of pharmaceutical products. In such situations, considering the humanitarian goals of CAMR, it is appropriate to allow private sector actors to disseminate imported products, even if such dissemination may seem to have "commercial purposes". Thus, subsection 21.14 (i) should also be struck from the legislation.

The goal of licensing companies is to provide eligible importing countries in need with low-cost pharmaceutical products that patent-holding companies are not providing. There is potential for diversion in the distribution process. This problem is not the fault of the licensing company, although diversion of exported products is a major concern to patent-holding pharmaceutical companies. The real question is how to allocate the cost of the unavoidable diversion that occurs in the course of distribution. If the cost is borne by the licensing company in the form of licence termination, the people in need of low-cost drugs are deprived of their sole source of affordable medication. Given the humanitarian goals of CAMR, this cannot be the appropriate way to allocate the costs of diversion.

The patent-holding companies argue that without subsections such as (f), (g), (h), (i) a significant amount of pharmaceutical products will be diverted to developed nations and sold illegally, thereby decreasing the price that the companies can charge for drugs in those nations. The amount of diversion in the past has not been significant. Prior to India bringing its legislation into compliance with TRIPS, it produced and exported massive quantities of generic drugs to countries in need.[38] Yet, the flow of diverted drugs to the black market of developed nations has not been significant so as to cause the price of patented drugs to fall in those nations. Thus it is possible to remove the aforementioned grounds of termination from the

[38] Anna Lanoszka, "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries" (2003). *International Political Science Review* 24(2) at 189.

legislation without seriously affecting the marketability of patented pharmaceutical products in developed markets.

The governments of developed nations can pursue more effective border control mechanisms. In this way the costs of diversion would fall on developed nations' governments and not on those in need of pharmaceutical products in eligible importing countries. This allocation of the costs of diversion is more in line with the goals of CAMR and the values of Canadians. The possibility of having a licence terminated under subsections (f), (g), (h), (i) significantly deters generic drug companies from participating in CAMR. Participation in CAMR is costly for generic drug companies who have to put many resources into the creation, production, and distribution of licenced products. If the subsections were amended in the manner suggested, participation by generic drug companies would increase and the humanitarian goals of CAMR would be closer to realization.

CONCLUSION

The process of accessing essential pharmaceutical products through CAMR can be streamlined and improved in various ways. Several elements of the current legislation can be removed: the double-standard between WTO Members and non-Members, Schedule 1, and the two-year term limit decrease CAMR's efficiency and scope. These can be completely eliminated from CAMR and it will remain TRIPS-compliant. Similarly, the requirements of a certified copy of the importing country's notification and of Health Canada Approval are unnecessary. The latter in particular can considerably extend the process of securing essential medicines through CAMR. The process should minimize delays given the urgency of the crises that CAMR is meant to address.

CAMR could be further improved by the clarification of "reasonable terms" in the application process, and of the grounds for termination. As they are currently written, these vague sections could lead to lengthy litigation, delaying the provision of pharmaceutical products. Unnecessary litigation could also be averted through the inclusion of an expeditious dispute resolution process, and through the elimination of the various sections referring to good faith that leave generic manufacturers vulnerable to legal action.

Finally, an increase in the flexibility of provisions designed to limit quantities would enable importers to adapt to changing needs. Those needs—the needs of the populations that CAMR is designed to aid—should motivate the review of the legislation throughout.

CAMR must work quickly. Last year, AIDS—which is but one of the many public health problems that CAMR was designed to address—caused the deaths of 2.9 million people.[39] Every day lives are lost as unnecessary administrative hurdles delay the provision of pharmaceutical products via CAMR. Time is of the essence.

[39] *AIDS Epidemic Update*, *supra* note 5 at 1.