



January 19, 2011

Dear Member of Parliament:

Re: Bill C-393 and Canada's Access to Medicines Regime

This letter is to advise you that Apotex Inc. continues to be supportive of the stated objectives of Canada's Access to Medicines Regime (CAMR). However, the legislation in its current form has proven to be unworkable.

You have before you Bill C-393 that seeks to create a modified approach. We continue to support this effort that would make this legislation workable in a sustainable manner. We are very concerned that an opportunity to reform CAMR may fail. The "Pledge to Africa" made in 2004 when creating CAMR is currently ensnared in a cumbersome regime that does not address the needs of those it was designed to help.

We have demonstrated our commitment in the past through our utilization of the cumbersome CAMR process and the delivery of anti-retroviral medications for the treatment of HIV/AIDS to the Ministry of Health in Rwanda. As a Canadian company, we remain committed to supporting global efforts to bring critical drugs to the developing world. We do not claim to be the only solution, just as CAMR or any other legislative approach cannot be the only solution. But we are *a* solution and, if CAMR is made workable, we are committed to using it as one tool to help address the dire need for more affordable medicines.

We urge you to consider some simple, fundamental changes to the existing CAMR that would immediately make it more workable and attractive for a company like Apotex to utilize in a sustainable manner. The two simple changes are as follows:

1. Make provisions for a "one license solution" whereby a single compulsory license is issued for a named product to supply the eligible countries already listed in the law. This is important because it removes the major barrier to initiating dialogue with countries by effectively providing to those countries a guarantee of what is available. As it stands, we cannot pursue supplying a product to an eligible country or countries under the current legislation without the country or countries first coming forward to make a request. Yet without a licence already issued to permit export to eligible countries, there is little incentive for a company such as ours to embark upon developing a product – and hence little likelihood of there being a product for an eligible country to request. This current requirement of first identifying a country, in order to seek a licence to supply that single country, is where most of the time delay occurred before Rwanda came forward to test the legislation – after Apotex had followed through on its commitment to NGOs to develop a product that it was known was needed in the field for patients. The current limitation of supplying a single country at a time, with each requiring a separate process, is also an inefficiency and disincentive to using CAMR that is embedded in the

current regime. In our view, the “one-licence solution” initially included in Bill C-393 addresses the key barrier that has limited to the use of CAMR to date.

2. Reject any arbitrary time limitation on the license. As any license issued under CAMR should be limited to supplying the quantities of that medicine needed by eligible countries, why should the timeline for delivery of the licensed quantity be time-limited? This is unreasonable and makes the management of logistics unnecessarily complex.

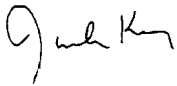
The above changes would make the use of CAMR a much more viable proposition from our perspective as a prospective supplier of more affordable medicines to eligible countries.

Apotex is committed to utilizing a legislative pathway that incorporates the above provisions. We have previously gone on record that should the legislation be modified effectively, our immediate next step will be to work with Health Canada, the medical community and Ministries of Health in the developing world to develop and provide a paediatric formulation of Apo-Triavir, the fixed-dose combination AIDS drug we provided to Rwanda. We also anticipate that, under a simplified CAMR, other countries would come forward under such a legislation to make requests for this and additional products that Apotex could supply.

I enclose a copy of our presentation regarding the limitations of CAMR and supporting the core reforms in Bill C-393 to the House of Commons Standing Committee on Industry, Science and Technology.

Should you have any further questions, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Jack Kay".

Jack Kay
President
Apotex Inc.

Submission to the
Standing Committee on Industry, Science and Technology

Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act

Apotex Inc.

October 26, 2010

Background

As far back as 2002, Apotex made it clear that we were able and willing to provide a Canadian contribution to the world-wide HIV/AIDS crisis. Initially, there were no humanitarian aid provisions available which would allow desperately needed drugs for critical diseases to be provided directly to regions affected. Despite Apotex's repeated approaches to various branches of the Canadian government, it appeared that barriers were insurmountable.

With the implementation of CAMR, some barriers were finally breached. A pathway to partially address the needs of the developing world was finally defined and Apotex immediately stepped forward to identify, develop and deliver the first drug under the provisions of that bill. That was a proud moment for Apotex and Canada. That moment was fleeting at best.

Juxtaposed to the chronic frustration of implementing the provisions of CAMR and the incessant stream of misinformation from those opposed to any meaningful evaluation of the effectiveness of the legislation, any optimism and hope that CAMR would result in an ongoing supply of critical drugs disappeared. A comment by a delegate to one of the international forums on this topic perhaps sums up the current state of CAMR best. Referring specifically to the legislation he said; "Canada has betrayed the hope Africa placed in her". Sobering words and words we must take seriously when considering the unmet medical needs that persist despite the world's best efforts to address critical diseases in the world's poorest regions.

Why CAMR isn't working

CAMR does not work and cannot work in its current form. Two shipments of drugs under one contract to one country in 6 years cannot be considered "working". Change is needed. There are those who would say that CAMR alone was not intended to solve the problem of access to critical medicines. Clearly there is no single solution to any global problem. However, should we not seriously consider every possible option, and in so doing, ensure that all efforts are optimized? Furthermore, CAMR is a singularly Canadian contribution to a global need.

The motivation of those who would criticize the efforts to improve legislation needs to be carefully considered. From an industry perspective, all of the patent holders involved in the first instance of CAMR's implementation were companies with head offices and decision makers outside Canada. To our knowledge, none of the decisions regarding granting of voluntary licences was made in Canada. Not one voluntary licence was granted. The terms put forward by patentees in the proposed voluntary licenses were unreasonable and could not be accepted by Apotex. The terms went beyond what was required under CAMR. It was a compulsory licence which released the product for shipment to Rwanda.

From the government's perspective (quoting Ms Colette Downie of Industry Canada speaking to this committee on October 7th), her comments "...at least we're concerned about, concerns for Canadian's access to innovative new medicines and research and development jobs", speak for themselves. These concerns seem to suggest that while giving verbal ascent to the provisions of CAMR, the patent holders are applying pressure to government to ensure that the legislation remains unworkable. Threatening disruption of supply or loss of Canadian jobs is posturing in the extreme and the Brand industry should be held fully accountable for the statements relayed by Ms Downie.

What is the objective of CAMR? If it is to ensure that it functions as intended and provides at least one avenue of access to critically needed drugs to the developing world, then the legislation needs to be amended. Clearly in its current form, as previously mentioned, CAMR does not represent the best interests of the developing world. It is of interest to note that in the intervening period between the granting of the compulsory licence for Apo-Triavir and today, we are not aware of any efforts by the patent holders to supply that critical combination of Lamivudine, Zidovudine and Nevirapine to countries in the developing world, countries that have indicated it is a highly effective and desired fixed dose combination.

If CAMR is not necessary, then why have the patent holders not stepped up to meet this obvious need? Clearly it is because there is no pressure on them to do so since CAMR is not working! They are counting on the fact that CAMR is impotent in its current form. Those who would claim otherwise need to answer the question, why, despite many serious enquiries, have no other countries stepped forward to make a request under the legislation as it now stands?

What needs to change?

Apotex remains committed as a Canadian company to supporting meaningful efforts by government and industry to find ways to provide much needed medications to the developing world. From our perspective, there are a few changes that should be considered essential in order for this legislation to be workable.

Firstly, in our opinion, the major failing of CAMR is the process required to initiate a request and the pressure that can be put on requesting countries as a result of that process. The same concerns expressed by Ms Downie are evident in the developing world and those regions are far more dependent on the goodwill of industry and industrialized nations than Canada is. The fact that countries cannot place a simple order or extend a tender for a specific product but have to initiate what is perceived to be a 'political' or legal process is in itself intimidating. That process needs to be changed.

In our experience with Rwanda, the major delay was the time it took to get a formal request from the country (see the attached chart). Critics point to that and try to say that is not a failing

of the bill but it is in fact the greatest failing of the entire process. The process is, for the most part, invisible to most agencies in countries that would access it. In many cases, even Ambassadors to Canada from those countries have never heard about it. Why is that? The Canadian government must take responsibility and take some meaningful action to promote the opportunity and facilitate the implementation of any legislative provisions.

Secondly, the efforts expended by Apotex to obtain voluntary licences from patentees were at best frustrating. Even under the existing provisions of CAMR, those negotiations are meaningless as there is a 30 day provision for granting of a compulsory licence should it not be possible to obtain one voluntarily. Why go through the machinations of a predictably futile process when even the existing legislation provides for the compulsory licence to be issued? This step should be revised to allow for the granting of a compulsory licence from the outset. This license should be on a product by product basis with appropriate monitoring of specific quantities and tracking of shipments country by country as part of that license agreement.

This is not about circumventing any controls as some would contend, but simply about eliminating unnecessary complications. The fact that a company could have terms of a licence in hand prior to entering into dialogue with a recipient country would greatly simplify the discussions and facilitate communication of product availability.

Should the Canadian government have limited resources to communicate the opportunity of utilizing CAMR, a company like Apotex can at least communicate that a key product is available. This step, in itself, would have taken at least 12 months off of the timeline for the initial shipments under CAMR and would have ensured that shipments would have continued. Rwanda has not made a subsequent request under the current legislation.

Thirdly, the time-limitation currently in place should be lifted. Delivery of products to the developing world is challenging at the best of times and there are multitudes of reasons why deliveries can be delayed. In addition, there is a need to manufacture and ship product in such a manner as to maximize shelf life. To arbitrarily set timelines that restrict manufacturing flexibility is to force situations where shelf life can be compromised. This time restriction also impacts the sourcing of raw materials which has a direct impact on costs.

Apotex has made the commitment that we would provide products at our cost and active ingredients are the major cost driver. Companies have to be able to maximize the scale of manufacturing in order to obtain the best prices. It should be noted that it was a competitive tender that Rwanda used when sourcing Apo-Triavir. We won that tender not only on quality of the product but also on price. Compulsory licensing as described above and removal of the time restriction on that licence will ensure competitiveness on pricing.

What is working under CAMR

What worked well under CAMR was the collaborative approach to product selection, development and approval. Contributing to this success was the willingness of the international and Canadian medical community to work with Apotex and Health Canada to develop and ultimately obtain approval for the product. In conjunction with these efforts, the contribution of NGOs was and continues to be invaluable as they have a vast knowledge and understanding of global needs on a country by country basis. These efforts must be recognized and encouraged.

The Health Canada approval, in our opinion, remains an important element of any legislation going forward. The approval of Health Canada is the assurance to recipient countries which do not have the infrastructure to review products themselves that these drugs meet the expected standards of quality, efficacy and safety. Furthermore, the WHO prequalification which follows Health Canada approval is, in our opinion, an essential part of the equation. We do not suggest any changes in the oversight process or activity ascribed to Health Canada under CAMR.

Apotex Inc.

As Canada's largest manufacturer of pharmaceuticals, Apotex supports a 'made in Canada' contribution to meeting the needs of the developing world. The "Pledge to Africa" that inspired CAMR has somehow become ensnared in a 'Regime' that seeks to protect the interests of everyone but those it was designed to serve. We have repeatedly stated that we are unlikely to utilize CAMR again in its current form. However, we continue to hope that the will to make meaningful changes will prevail, and as Canadians, we can once again restore the hope that Africa and other nations have placed in us.

Thank you.

CAMR: In Practice

