

Remarks for

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House of Commons  
Standing Committee on Industry,  
Science and Technology

“The Apotex Experience with the  
Canada’s Access to Medicines Regime”

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Thank you for allowing Apotex the opportunity today to present our real life experience of trying to maneuver the Canada's Access to Medicines Regime (CAMR) legislation.

The Apotex Group is a leader in the research and development of generic, innovative and biotechnology medicines in this country. We plan to spend \$2 billion over the next 10 years on R&D and, as we speak, we have over 600 medicines under development. With close to 5,000 employees, we plan to add another 350 to expand our production capacity from 1 billion tablets and capsules per month to 1.4 billion. Over 300 medicines we presently manufacture are exported to 115 countries.

All of this is to meet our core Apotex value, which is to provide access to life saving affordable medicines. In Africa hundreds of thousands of people die needlessly from HIV/AIDS every year because they do not have access to such medicines.

The reason is simple; the multinational pharmaceutical industry does not like to reduce their prices and it's better to sell it to industrialized countries where they can charge higher prices.

After listening to a speech from Stephen Lewis, we made a corporate commitment to do something about the problem. In 2002 we made an offer to the Federal government of the day that we would produce 5 anti-retrovirals at our cost, as long as they got them where it could be used in Africa.

The government never even offered to look at our proposal. Part of the problem was that there was no mechanism to facilitate the process and a lack of infrastructure for effective distribution.

In the meantime, millions continue to die from HIV/AIDS.

Then in 2003, Bill C-9 was tabled and hope was high that something was going to get done.

Here is a recap of our experience: Working in consultation with Médecins sans frontières (MSF), who outlined the HIV/AIDS medicines that were in critical need, they advised us that a combination drug of Lamivudine, Zidovudine (Combivir), plus Nevirapine was needed. We started working on Apo-TriAvir; a special R&D team was assigned on this project and they doubled their efforts working weekends and overtime to complete the submission dossier. Many worked on their own because they wanted to do something important for the HIV/AIDS patients in Africa. This could potentially save millions of lives and Apotex was committed to providing Apo-TriAvir at our cost.

At the same time, Health and Industry Canada defined an expedited approval route.

Work on the fixed dose combination began April 2005 and the submission dossier was finalized in December 2005. The dossier was approved by Health Canada in June 2006 and World Health Organization (WHO) pre-qualification was achieved following the approval.

This assured recipient countries of : Efficacy and Safety; Authenticity and Availability.

Apotex invested over \$2 million to date on the research and development of the drug.

Yet, having done all this to get this important HIV/AIDS medicine ready, the real problem is the legislation; the CAMR requirements are impossible to navigate. First it's a voluntary license vs. a compulsory license; it requires the recipient country to be identified up front and they need to initiate the request. The entire burden is left on the shoulders of the poor countries that do not have the expertise or resources. The legislation is designed for pharmaceutical companies doing business in the industrialized world, not Africa.

The effectiveness of the legislation is compromised by the lack of clarity. Maybe the objective of CAMR has to be clearly defined "Quality medicines for critical diseases in a timely manner".

The current complex legislation tries to "balance" the interests of Big Pharma first. Why? We need to get our priorities right and focus on those who are dying every day from AIDS in Africa. This legislation perpetuates the human crisis without getting anything done, also, there is nothing stopping the multinational pharmaceutical industry from unilaterally making these drugs available, but they have not. All their efforts have been focused on impeding the legislation.

In conclusion, the following are our recommendations – having experienced the process:

We need to move to a defined compulsory license upon regulatory approval. This will speed up the process and limit legal costs, which can be substantial.

The ownership of the process must be transferred and the Canadian Government needs to move from “Facilitator” to “Implementer”. It should not be left solely on the back of Canada’s generic pharmaceutical industry to get this done; the government needs to take it on, or at the very least help us.

As a private company, Apotex has more latitude to work on products like this versus the publicly-traded for-profit-based industry. Let me say clearly that pricing is not the only issue under CAMR.

There are government agencies like CIDA already established that can manage supply agreements.

And the idea we are tabling is to do “not for profit” development and manufacturing of needed medicines at existing government sponsored, university based facilities under compulsory license agreements. Apotex could collaborate to support the development, training and production at these facilities.

At the end of the benefits for this proposal is a

1. clear purpose
2. clear ownership and accountability
3. sustainable process and
4. transparency

It is time, Ladies and Gentlemen, to do something to stop the suffering in Africa and developing countries. It is in your hands to make a positive impact on humanity. Let's not wait until another million people die. We can do it if there is the political willpower. No company will be able to do anything with the way the present legislation is structured today.

Thank you