Canadian Generic Pharmaceutical Association

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Transparency International Canada, Inc.

Aid Versus Corruption: Getting Your Dollars to the World's Poor

What are the issues, today?

Jim Keon, President
Canadian Generic Pharmaceutical Association (CGPA)

Wednesday, June 10, 2009

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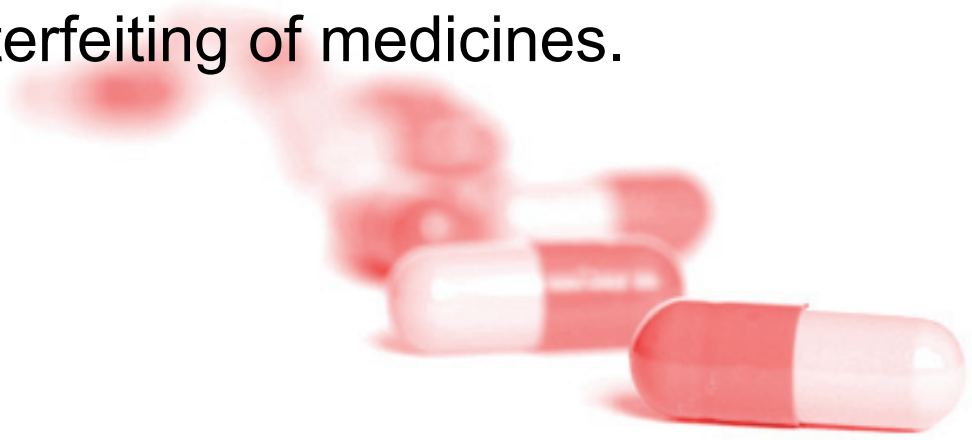
What are the issues, today?

- The role of trade associations in Canada and internationally in promoting/protecting the interests of their members companies.
- The failed promise of Canada's Access to Medicines Regime.
- The international counterfeiting of medicines.



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The Role of Trade Associations

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Canadian Generic Pharmaceutical Association

Who We Are:

For more than 50 years, Canada's generic pharmaceutical industry has played a vital role in the country's health-care system and its economy by providing safe, effective, proven alternatives to more expensive brand-name medicines.

- CGPA represents manufacturers and distributors of finished generic pharmaceutical products in Canada.
- Generics saved our healthcare system $3 billion in 2008.
- Generics filled 52% of prescriptions in Canada in 2008 for less than one-quarter of our total drug bill.
- Our industry employs more than 11,000 Canadians in highly-skilled jobs.
- 40% of Canadian-made generics are exported.
- CGPA is a founding member of the International Generic Pharmaceutical Alliance (IGPA) -- along with generic associations in the U.S., Europe, India and Japan. Brazil, Jordan, South Africa and Taiwan are observer members.

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Vision 2012:

CGPA will create the best environment to build a sustainable world-class Canadian generic pharmaceutical industry, thus increasing the availability of high quality affordable generic medicines for Canadians and the international community.

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Role of Trade Associations

- Effective regulatory environment
  - Create more certain and timely access to markets through clear government rules and practices.
- Long-term sustainability of industry
  - Create conditions to support investment, growth, adequate returns and quality affordable products.
- Stakeholder relations
  - Improve perceptions and support for industry.
  - Work towards common goals.

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Failed Promise:
Canada's Access to Medicines Regime

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Failed Promise:
Canada's Access to Medicines Regime (CAMR)

- In 2003, Canada announced it would be the first country to implement the Doha Declaration to allow Canadian generic company to obtain a license to produce and export drugs for humanitarian reasons.

- The process and outcome became a bitter disappointment:
  - Unnecessary concessions were made to brand-name drug makers from the beginning.
  - The legislation imposed onerous requirements on a generic company seeking to obtain and use a license to export drugs for humanitarian purposes – far beyond WTO requirements.
  - CGPA and NGOs identified a number of fundamental flaws with the legislation during the committee hearings, but calls for improvements were ultimately ignored.

"This drug-by-drug, case-by-case approach makes no sense. Such a convoluted and drawn-out system can never respond to the urgent needs of patients in developing countries who are dying each day from preventable and treatable diseases."

–Rachel Kiddell-Munroe, formerly of MSF Canada

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Failed Promise: Canada's Access to Medicines Regime (CAMR)

- Canadian generic drug maker Apotex took the initiative to test CAMR.
- After four years Apotex was finally able to provide a single shipment of its triple-combination AIDS drug to Rwanda in the fall of 2008. A second and final shipment is planned for fall 2009.
- Given the complexities of the regime, the company has indicated it is not able to use CAMR again unless the process can be significantly improved.

"I don't know whether we did the developing world a favour or disservice by getting that first shipment of TriAvir out. It seems to have appeased the conscience of the legislators and of the brand industry, and let them think we don't need to do anything else. That's unconscionable."

- Bruce Clark, Senior VP of R&D, Apotex

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Failed Promise:
Canada's Access to Medicines Regime (CAMR)

Opportunity to Improve CAMR:

- Two Private Member's Bills have been tabled in Parliament, which propose much-needed improvements to CAMR:
  - Bill S-232 - sponsored by Liberal Senator Yoine Goldstein
  - Bill C-393 - sponsored by NDP Health Critic Judy Wasylycia-Leis

- Both Bills are supported by CGPA and a number of NGOs, including Canadian HIV/AIDS Legal Network, the Stephen Lewis Foundation, Oxfam, and many others.

"If the federal government simplifies the process, then Apotex pledges to work with NGOs and Health Canada to research, develop and deliver a generic fixed-dose anti-retroviral medication for treating children with HIV. At this time, this drug is not made by any brand-name company, but it has the potential to save the lives of thousands of children."

– Jack Kay, President, Apotex

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Counterfeit Medicines

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Counterfeit Medicines

- World Health Organization (WHO) defines a counterfeit drug as:

"a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. ***Counterfeiting can apply to both branded and generic products*** *and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."*

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Counterfeit Medicines

- Global public health concern:
  - Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest.
  - Many countries in Africa and parts of Asia and Latin America have areas where more that 30-50% of the medicines on sale are estimated to be counterfeit. This is also where criminals tend to produce counterfeit medicines.
  - Those living in poverty in developing and least developed countries are most likely to come into contact with counterfeit medicines.

- Jurisdictions with stringent regulatory requirements, including Canada, have a low risk of counterfeit medicines reaching consumers. Illegal online pharmacies pose the greatest risk.

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Counterfeit Medicines

Anti-Counterfeiting Trade Agreement (ACTA)

- Has its origins in the frustration of some developed countries with the WTO process (US, EU, Canada, Japan, etc.)

- Negotiations focus on intellectual property (IP) measures.
  - Trademarks and copyright are primary focus but EU wants to go farther (patents, etc.)

- Inappropriate to attempt to include counterfeit medicines through an IP agreement.
  - Significant public health concern – not a business issue.
  - Activities conducted by criminals – not legitimate companies.
  - Excludes the very countries that are largest producers and consumers of counterfeit medicines.
  - Brand-name drug companies attempting to confuse generics with counterfeit drugs in their latest push to gain even greater intellectual property protections.

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Counterfeit Medicines

Border Measures

- Border measures represent a new threat to the free flow of legitimate generic drugs around the globe.
- Recent seizures of legitimate generic drugs in the EU while in transit from India to developing and least developed countries.
- Seizures were based on domestic IP laws, even though the drugs were just passing through.
- Major concern for NGOs, such as MSF, who have storage and distribution facilities in the EU.

The WHO is concerned:

"..the recent events related to the handling of medicines in transit and the potential consequences for the supply of medicines in developing countries are of major concern to the organization…. Ensuring that the interests of trade and health are appropriately managed, also means that the flow of legitimate medicines, including generic medicines, is not impeded." (March 2009)

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Counterfeit Medicines

A More Appropriate Approach

- Focus on truly global initiatives, like the IMPACT initiative.
- Remove barriers to free flow of legitimate generics.
- Make improvements to CAMR and similar initiatives in other jurisdiction to improve access to high quality essential medicines in developing and least developed countries.
- The most developed countries should provide assistance to developing and least developed countries in creating stronger domestic regulatory and legal systems.
- Developed countries should properly resource their own existing measures (more inspectors, traceability, etc.)

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