

**Submission to the
Government of Canada**

Anti-Counterfeiting Trade Agreement (ACTA)

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

Canadian Generic Pharmaceutical Association

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Canadian Generic Pharmaceutical Association

4120 Yonge Street, Suite 409, Toronto, Ontario, Canada M2P 2B8 Tel: (416) 223-2333 Fax: (416) 223-2425

www.canadiangenerics.ca

Introduction

The Canadian Generic Pharmaceutical Association (CGPA) represents Canada's generic drug industry – a dynamic group of companies that specialize in the production of high quality, affordable generic drugs and fine chemicals and in conducting the clinical trials required for government approval of generic drugs. For more than 50 years, Canada's generic pharmaceutical industry has played a key role in our country's economy and health care system.

Canada is home to a vibrant generic pharmaceutical industry, which employs more than 11,000 Canadians in highly-skilled jobs. Most of the generic drugs sold in Canada are made in Canada. In addition, about 40% of domestic production is exported to more than 120 countries around the globe, with a large percentage exported to the United States. The industry expects to increase employment to 21,000 Canadians by 2012, and increase exports to 50-60% of domestic production over this same period. The industry also makes significant investments in domestic R&D activities to the tune of 15% of Canadian sales.

The generic pharmaceutical industry also makes significant contributions to the Canadian health care system. Drug costs are the fastest rising cost for Canadian governments and for employers that sponsor drug benefit plans for their employees. The use of lower-cost generic prescription medicines saves Canadian governments, employers and consumers more than \$2.6 billion every year. Even though generic drugs are dispensed by pharmacists to fill more than 49.9% of all prescriptions in Canada, they account for only 21.9% of the \$19.55 billion that Canadians spent on prescription medicines in 2007.

As a pharmaceutical stakeholder that is concerned about the public health risk posed by illegal counterfeit drugs, CGPA welcomes the opportunity to provide comment to Government of Canada's participation in the Anti-Counterfeiting Trade Agreement (ACTA) negotiations.

Of particular concern to the generic pharmaceutical industry, the proposed content for this agreement does not indicate the discussions will address appropriate limitations on the scope and reach of intellectual property enforcement mechanisms. Patent disputes during the normal legitimate business development of a product could become – in the context of ACTA – a crime related to counterfeiting instead of remaining a private civil matter between two companies.

Such a change would have dire consequences for Canadian consumers, payers, governments, the economy and the generic pharmaceutical industry, and would not be successful in targeting counterfeit medicines. In fact, the resulting increase in drug costs through monopoly drug prices could lead Canadians to seek lower-cost alternatives through less-than-reputable sources, which in turn could put them into contact with counterfeit medicines.

As such, it is CGPA's position that patent enforcement should not be considered during ACTA negotiations as a tool to fight counterfeiting.

Is ACTA Necessary?

Counterfeiting is a concern for Canadians, and CGPA supports international discussions regarding measures to combat counterfeiting.

CGPA questions the need for an additional trade agreement for intellectual property that is outside the scope of the traditional multinational venues for establishing standards of international

intellectual property law. The countries currently involved in ACTA negotiations have sophisticated intellectual property regimes with robust enforcement mechanisms, and the generic pharmaceutical industry is unaware of any compelling arguments supporting the need for an additional agreement.

CGPA is concerned that the final agreement could be inconsistent with, or contradictory to, current international intellectual property policy interests, and could have unforeseen and negative consequences. It is important for ACTA negotiators to recognize that balanced intellectual property policies are the best means of advancing Canada's interests, both domestically and internationally. As such, ACTA discussions should reflect existing intellectual property enforcement mechanisms.

What Are Counterfeit Medicines?

As defined by the World Health Organization (WHO), a counterfeit drug is:

“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.”¹

The use of counterfeit medicines can result in unexpected side effects, dangerous drug interactions, incorrect dosages, allergic reactions or the worsening of medical conditions. **It is important to note that both brand-name and generic drugs can be counterfeited. As such, a focus on patents in combating counterfeit medicines is inappropriate.**

Regional Prevalence of Counterfeit Drugs

WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) has observed that the prevalence of counterfeiting is greatest in regions where regulatory and legal oversight is weak.² IMPACT estimates that more than 30% of medicines for sales in parts of Africa, Asia and Latin America are counterfeit, and the rate for all developing countries is estimated to be between 10% and 30%. Medicines purchased over the Internet from sites that conceal their physical addresses have been found to be counterfeit in 50% of cases.

In contrast, IMPACT has found that “most developed countries with effective regulatory systems and market control (e.g. USA, EU, Australia, Canada, Japan and New Zealand) currently have a very low proportion, i.e. less than 1% of market value.”³ As Canada's Criminal Intelligence Service has observed, “Canada has a standardized, highly regulated pharmaceutical and public health care system that is largely affordable to most Canadians. This significantly lessens any potential market for illegitimate supplies of pharmaceuticals in Canada.”⁴

¹ <http://www.who.int/medicines/services/counterfeit/overview/en/>

² <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

³ <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

⁴ http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals_e.html

While counterfeit medicines represent a public health concern across jurisdictions, the domestic prevalence of these products is relatively low. As such, it is imperative that any additional measures to combat these illegal products involve strengthening existing regulatory controls and appropriately targeting the criminals engaged in counterfeit activities – without creating unintended consequences.

Effective Measures to Combat Counterfeit Drugs

IMPACT, which includes representation from both the brand-name and generic pharmaceutical industries, has made a series of recommendations on how countries can deal with the problem of counterfeit pharmaceuticals.⁵ These include stringent regulatory procedures, improved training for customs officers and quality control inspectors, improved policing, and increased public and health professional awareness. A number of these areas will be considered in the context of the ACTA negotiations.

Patent enforcement was not regarded as an appropriate measure to combat counterfeit drugs by IMPACT. Counterfeit drugs are regarded as a public health issue in which organized or local criminals carry out counterfeit activities, rather than infringements of private rights.

Scope of ACTA Enforcement Provisions

The Department of Foreign Affairs and International Trade issued a news release on October 23, 2007 regarding its participation in the ACTA negotiations, which states:

“The main objective of an ACTA would be to develop international standards to better combat the trade in counterfeit trademarked and pirated copyright goods. Provisions would focus on international cooperation, enforcement practices and legal frameworks, including enforcement systems.”

The need to reform Canadian trademark and copyright laws to better combat counterfeiting and piracy has been a topic of public discussion in recent years. To this end, both the House of Commons Standing Committee on Public Safety and the Standing Committee on Industry, Science and Technology released reports in 2007 that recommended amendments to the *Trade-marks Act* and the *Copyright Act*.

The ACTA Fact Sheet published by the Government of Canada suggests, however, that ACTA is taking a much broader approach by generalizing measures to combat counterfeiting and piracy as applicable to all forms of intellectual property rights, including patents.

CGPA is concerned that common enforcement practices proposed by ACTA could be misapplied and misused by intellectual property holders against legitimate competition in the area of patents.

1. The Counterfeiting of Pharmaceutical Products is a Public Health Issue

Counterfeit medicines are drugs that are not approved for sale by a domestic regulator. These products are produced by criminals and represent a serious risk to public health.

⁵ International Medical Products Anti Counterfeiting Task Force (IMPACT). Principles and Elements for National legislation against Counterfeit medical products. Text endorsed by IMPACT General Meeting, Lisbon 2007.

Both brand-name and generic medicines can be the target of counterfeiters and, as such, counterfeit medicines do not necessarily represent an infringement of domestic patents.

Criminalizing legitimate patent disputes would not address the serious public health risk posed by counterfeit products, and would have serious a serious negative impact on the affordability of Canadian health care and Canada's generic pharmaceutical industry.

2. Patent and Counterfeiting Issues Should Not Be Confused

There are many genuine disputes over the validity of patents. Under the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act*, brand-name companies delay competition by taking a generic company to court and alleging a patent has been infringed. In the vast majority of cases, however, the courts decide that a patent has not been infringed and the generic product should proceed to market.

Patent disputes are an everyday commercial risk for both brand-name and generic companies due to the technical complexities of drug development and the domestic regulatory system. Patent disputes are – and must remain – a private civil matter between two legitimate companies. The products in question are not counterfeit – they are produced by legitimate companies, have received regulatory approval by Health Canada, and are sold in regulated markets.

In contrast, copyright and trademark infringements are generally deliberate criminal acts. The two concepts should not be confused.

Any potential confusion between generic drugs and counterfeit medicines must be avoided.

Comparator	Competition from Generic Company	Counterfeiting by Criminal Organization
Organization	Legal business entity.	Criminals.
Market	Operates within the highly regulated Canadian marketplace for pharmaceuticals.	Operates illegally on the open market.
Health and safety risk	No health or safety risk as products have been reviewed and approved for sale by Health Canada.	Serious risk to public health as counterfeit drugs have not undergone regulatory review and are not approved for sale in Canada.
Labeling	Products are sold under their own label. The labels for both brand-name and generic drugs must be reviewed and approved by Health Canada.	Products usually contain fraudulent labels. The counterfeit product is generally misrepresented as a legitimate brand-name or generic drug product.
Legal Jurisdiction	Civil disputes may arise between brand-name and generic companies regarding the validity of patents under Canadian law.	Criminal intent throughout the supply chain.

3. Article 61 of TRIPS

Article 61 of TRIPS makes an important distinction between trademarks, counterfeiting and copyright piracy on the one hand and other IP rights disputes on the other. This clear division should be maintained in discussions on measures to tackle counterfeiting.

Abolishing the internationally accepted distinction between piracy/counterfeiting and alleged infringements of patent rights would set a dangerous precedent.

4. Public Resources Should Be Used to Fight Crime – Not Finance Patent Disputes

Governments around the world are under immense pressure to deal with organized crime. Diverting public resources to deal with corporate disputes over patents is not justifiable, and would place scarce resources at the disposal of brand-name drug companies to pursue the legal actions they would otherwise have to finance themselves. It is essential that public resources be directed to where the problem is indeed criminal and a risk to public health and safety.

A more effective approach to combating counterfeit medicines is to place a strong emphasis on the recommendations made by IMPACT in areas such as public education, border measures, inspections, and policing.

5. Serious Consequences if Patents Not Excluded from ACTA

Canada is already home to one of the most robust intellectual property regimes in the world, and provides unique benefits to brand-name companies that are not available to other Canadian patentees or to pharmaceutical patentees in other jurisdictions. CGPA and Canada's generic pharmaceutical industry support patent rights and the right of any pharmaceutical company – brand or generic – to recoup their investments and turn a profit to help grow and sustain their business.

Balanced intellectual property policies are the best means of advancing Canada's interests, both domestically and internationally. CGPA does not support the abuse of the intellectual property system to extend monopolies for brand-name pharmaceutical companies, nor do we support the expansion of intellectual property rights in the area of patents under the guise of combating counterfeit medicines. Such measures would be ineffective and represent a generous gift to brand-name pharmaceutical companies at the expense of Canadian consumers, payers, and the generic pharmaceutical industry.

The following are just a few of the consequences Canadians could expect if pharmaceutical patent disputes were to become a crime related to counterfeiting instead of remaining a private civil matter between two companies:

Chill Effect on Generic Competition

The Canadian health care system benefits greatly from the willingness of generic companies to develop products when all relevant patents have expired. While civil litigation – normally commenced by a brand company – often follows, the courts find the remaining patents are invalid in the majority of cases. If patents were to become a crime relating to counterfeiting, the risk for a company to develop a generic version of a product covered by frivolous or invalid patents would simply be too great.

Generic companies would be forced to delay product development until all patents expire, even if those patents were potentially invalid or would not be infringed. This would have the effect of delaying generic competition from a few years to more than a decade.

Extension of Brand Monopolies

The absence of timely generic competition would increase brand market monopolies, even when the only active patents covering a product are invalid. The extended monopoly could last from a few years to more than a decade for each product. This gift to the brand-name pharmaceutical industry would do nothing to achieve the goal of combating counterfeit medicines.

Increased Drug Costs

Generic drugs play an important role in the affordability of the Canadian health care system and increasing patient access to life saving treatments. Delays in generic competition resulting from such a change would unnecessarily cost provincial governments, taxpayers, employers that sponsor drug plans and patients millions of dollars each year.

Increased Attractiveness to Counterfeiters

As noted earlier in this submission, the instance of counterfeit medicines in Canada is low due to our highly regulated pharmaceutical and public health care system, which is affordable to most Canadians. As drug costs rise due to the extension of monopoly prices for brand companies through unchallenged invalid patents, counterfeiters would see increased opportunities to target Canadian consumers.

Harm to Generic Pharmaceutical Industry

Canadian generic companies operate in a highly competitive global environment. Companies would be left with no choice but to re-examine their significant investments in Canada in comparison to other, more competitive jurisdictions. This could have a negative impact on employment, R&D spending and current and future investments in the Canadian economy.

Generic Export Markets

Canadian generic companies export products to more than 120 countries worldwide. It is essential for generic companies to be able to access international markets as soon as they open up. If Canada is subject to stricter domestic intellectual property requirements than its trading partners, Canadian generic companies will simply be unable to compete on the international stage. Production would move to countries that do not have such a heavy-handed and excessive intellectual property regime.

Conclusions

CGPA and Canada's generic pharmaceutical industry support appropriate and targeted measures to combat the prevalence of illegal counterfeit drugs worldwide.

While we believe the Government of Canada's intent is to expand enforcement provisions for trademarks and copyright only, CGPA is concerned that entering into a trade agreement that does not clearly distinguish between trademarks/copyright and other forms of intellectual property would ultimately have serious unintended consequences for all Canadians.

Expanding the enforcement provisions for patents would be a completely ineffective measure in combating the prevalence of counterfeit medicines in Canada, and would undermine well-established policies and business practices that support competition in the Canadian pharmaceutical industry. As such, patents should be explicitly excluded from the scope of ACTA.

The Canadian Generic Pharmaceutical Association thanks the Government of Canada for this opportunity to comment on Canada's involvement Anti-Counterfeiting Trade Agreement. The Association remains available to assist the Government of Canada in the development of effective measures to combat the counterfeiting of pharmaceuticals, both at home and abroad.

For further information contact:

Jim Keon
President
Canadian Generic Pharmaceutical Association
416-233-2333 | jim@canadiangenerics.ca

Jody Cox
Federal Government Relations
Canadian Generic Pharmaceutical Association
613-218-8839 | jody@canadiangenerics.ca

Overview of Canada's Generic Pharmaceutical Industry

Scientific Employment

Canada's generic pharmaceutical industry employs approximately 11,000 Canadians in well-paid, highly skilled jobs in laboratories, production facilities and other operations. Generic companies are actively looking to secure new markets and expand their Canadian employment base. CGPA member companies have committed to doubling the industry's employment in Canada over the next five years.

Research and Development

The generic industry fuels the economy through direct capital expenditures and spending on research and development. CGPA member companies invest approximately 15% of sales (\$450 million) in R&D in Canada each year. Brand-name pharmaceutical companies in Canada reinvest only 8.3% of sales in R&D and only 2% of sales on basic research and development despite enjoying an intellectual property regime that exceeds Canada's international trade requirements.

Manufacturing

Most brand-name drugs sold in Canada are shipped into the country. Most generic drugs sold in Canada are made right here. In fact, the majority of the pharmaceutical manufacturing capacity that exists in Canada is generic.

Exports

The generic pharmaceutical industry has built a successful international business over the years, and today generates 40% of its sales volume from exporting high quality made-in-Canada pharmaceuticals to more than 120 countries around the globe. Due largely to the imports of brand-name companies, Canada has a significant trade deficit in pharmaceuticals of more than \$5.7 billion. CGPA member companies are actively seeking ways to expand their international export markets, but both domestic and international barriers are hampering the expansion of generic exports.

Competition

An October 2007 report by the Competition Bureau confirms Canada's generic pharmaceutical industry is highly competitive and plays an important role in controlling prescription drug costs. The study also expressed concern that the savings produced by this competition may not always be reflected in the final prices at pharmacies.

Generic Drug Prices

In Canada, provincial governments are responsible for delivering public drug benefit programs and setting the prices they will reimburse pharmacies for generic pharmaceuticals. The provinces of Ontario and Quebec have recently made significant changes to the way in which generic drugs are priced in their jurisdictions, which has already generated hundreds of millions of dollars of further cost savings. Other provinces are currently reviewing the methods for determining reimbursement pricing for generic drug products in their jurisdictions.

Contributions to Canadian Health Care

The generic pharmaceutical industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 49.9% of all prescriptions but account for only 21.9% of the \$19.55 billion Canadians spend annually on prescription medicines.

Widening Prescription Gap

The gap in Canadian generic prescribing practices compared to the United States is staggering. Lower-cost generic drugs filled 49% of all prescriptions in Canada in 2007, compared to 67% in the United States. This 18% gap is the largest ever recorded and represents an increase of 2% compared to 2006 levels. Canadians could save more than \$750-million on the cost of prescription medicines in the first year alone if the use of generic drugs increased to levels in the United States.

Product Safety

Approved by Health Canada, generic drugs are low-cost versions of brand-name drugs that are produced by several manufacturers once the 20-year patents expire on the brand-name versions. Generic drugs are identical or bioequivalent to higher-priced brand-name versions in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. CGPA member companies also conduct extensive post-market surveillance activities that meet the most stringent of global pharmacovigilance standards to ensure ongoing patient safety.