

Submission to the
**Standing Committee on Industry,
Science and Technology**

Study on Science and Technology

GENERIC DRUGS.



SAME QUALITY. LOWER PRICE.

Canadian Generic Pharmaceutical Association

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Overview of Canada's Generic Pharmaceutical Industry

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.

The industry plays an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 49% of all prescriptions but account for only 20.7% of the \$19-billion Canadians spend annually on prescription medicines.

There are no differences in the quality, purity, effectiveness and safety of generic drugs and higher-priced brand-name drugs. All drugs sold in Canada must be approved by Health Canada, and each product must meet the strict regulations established by the *Food and Drugs Act*.

Scientific Employment

Canada's generic pharmaceutical industry employs approximately 10,500 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 (R&D). CGPA member companies invest approximately 15% of sales (\$450 million) R&D in Canada each year. Brand-name pharmaceutical companies in Canada reinvest only 8.1% of sales in R&D and less than 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 have committed to increasing exports from 40% to 50% over the next 5 years, but both domestic and international barriers are hampering the expansion of generic exports.

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. 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 the levels of the United States.

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. 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 resulted in hundreds of millions of dollars in further cost savings. Other provinces are currently reviewing the methods for determining reimbursement pricing for generic drug products in their jurisdictions.

Intellectual Property and Pharmaceuticals

Intellectual property protection is set by federal law and is shaped by international trade agreements. Brand-name drugs have 20 years of patent protection in Canada. During that time, only the patent holder can produce the drug. After the patent expires, other manufacturers can apply to Health Canada to produce and market generic versions.

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. There is a prevailing misconception, however, that long periods of intellectual property protection are necessary to encourage and support innovation in the pharmaceutical industry.

CGPA suggests the Committee focus on measures to provide balance to Canada's intellectual property regime for pharmaceuticals by ensuring that it meets – but does not exceed – our international trade obligations, thus appropriately rewarding investments while allowing competition to spur further innovation and provide better value for Canadians.

Policy Considerations

Historical data from the Patented Medicine Prices Review Board (PMPRB) reveals that increased intellectual property protection in the pharmaceutical sector has not led to increased domestic R&D spending.

- **Big Pharma breaking its R&D commitment to Canadians**

With the adoption of the 1987 amendments to the *Patent Act* (Bill C-22), Canada's Research Based Pharmaceutical Companies made a public commitment that brand-name drug manufacturers would increase their annual R&D expenditure to 10% of sales revenue by 1996. According to PMPRB's 2006 Annual Report, the brand-name companies' R&D-to-sales ratio is below the level promised for the sixth consecutive year. These companies are enjoying increased market monopolies without being held accountable for breaking their R&D investment commitment to Canadians.

Pharmaceutical patentees spent only 8.1% of their revenues on R&D in 2006, below the 10% threshold the industry committed to in 1987. It should also be noted that this figure includes research expenditure funded by government grants. If the government-funded component is excluded, the R&D-to-sales ratio for 2006 actually drops to 7.9%.

- **Less than 2% of sales revenue spent on basic research into new drugs**

While total R&D spending by pharmaceutical patentees was \$1.2-billion in 2006, spending on basic research for new drugs was only \$232-million – or less than 2% of their Canadian sales revenue.

- **Canada's pharmaceutical R&D spending well behind other countries**

The ratio of R&D to domestic sales in Canada remains well below values in the United States and Europe. According to the PMPRB's 2006 Annual Report, the Canadian ratio in 2000 was just 10.1%. Only Italy (6.2%) had a lower ratio in that year. Switzerland had the highest ratio at 102.5%, followed by Sweden at 44.4%. France, Germany and the United States were in the 16% to 18% range, while the U.K. was more than double (35.1%). A very similar pattern emerges in the ratios for 2004 – Italy (6.6%) remained at the bottom of the range, with Canada in the second lowest position at 8.3%. Ratios in all other comparator countries were again well above Canada's ratio.

- **Most “new” drugs not truly innovative**

There were 99 new patented drug products, or DINs, for human use introduced in 2006. Some are one or more strengths of new active substances (NAS) and others are new presentations of existing medicines.

In 2006, there were 29 new active substances. Of these, only 4 were Category 2, which the PMPRB defines as “*the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drugs products, often referred to as ‘breakthrough’ or ‘substantial improvement’*”. The vast majority (21 new active substances) were Category 3, which the PMPRB defines as “*a new drug or new dosage form of an existing medicine that provides moderate, little or no therapeutic over existing medicines.*” The remaining 4 new active substances were not categorized as of March 2007.

Of the 131 new active substances introduced in Canada from 2001 to 2006, only 11 were categorized by the PMPRB as a “breakthrough” or “substantial improvement” over existing drug products.

Notice of Compliance Regulations

Bill C-91 brought in the *Patented Medicines (Notice of Compliance) Regulations* in 1993. Through a practice known as “evergreening”, brand-name pharmaceutical companies were able to extend their market monopolies by using the automatic stay provision in a manner that was not intended when the *Regulations* were conceived.

Brand-name drug companies learned to list many patents on the same medicine and stagger the listing of these patents so they would have different expiry dates. Each one of these additional patents could then be used to trigger an automatic block of a generic competitor. These legal manoeuvres could unfairly block generic competition, sometimes for several years, and force governments and consumers to pay monopoly drug prices for longer than they should.

The federal government moved to close the loopholes that allowed evergreening in October 2006. There is widespread agreement that the practice of evergreening was never intended by the *Regulations* and tipped the balance too far in favour of the brand-name companies at the expense of Canada’s health-care system and to the detriment of domestic generic drug companies. Even so, in attempting to close the loopholes, the federal government made additional changes to the *NOC Regulations* and *Food and Drugs Act Regulations* that altered the balance again in favour of the brand-name drug makers.

An October 2006 change to the *NOC Regulations* eliminated the ability of a generic pharmaceutical company to claim against a brand-name drug company for profits made by the brand company through unfair delays of generic competition through misuse of the automatic stay provision. This right was included in Section 8 of the *Regulations* as a crucial protection for generic drug companies and consumers. Without it, there is now no downside for a brand-name drug company to unfairly delay generic competition, and no benefit for a generic company to pay for costly litigation even though it has been harmed. As a result, monopolies will be unfairly extended without limit despite there being no patent that would be infringed.

The automatic stay provision is unique to patentees in the pharmaceutical industry and remains in the *NOC Regulations*. The *Regulations* have been described as a “draconian regime” by the Supreme Court of Canada. Past case law shows the generic wins the vast majority of these cases when they finally reach a court hearing, during which time the brand-name company has had a wrongful monopoly during the automatic stay.

The Government of Canada should take measures to ensure the system is not abused prior to a court hearing. Appropriate legal liability for brand-name pharmaceutical companies that misuse the *Regulations* must be reintroduced.

Longer Market Monopolies Through Increased “Data Exclusivity”

Data exclusivity extends a brand-name company’s market monopoly over a product. Data exclusivity is independent of the patent regime and operates as a separate system of government sanctioned and enforced market monopoly to prevent a generic competitor from entering the market.

The October 2006 amendments to the *Food and Drug Regulations* greatly expanded another regime to provide brand-name drug companies with an 8.5 year (8 years plus 6 months pediatric exclusivity) ban on competition, even for non-patented drugs. Canada’s pre-October 2006 data protection regime of 5 years was in full accordance with international trade agreements such as the North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Right (TRIPS) agreement, and should have been left alone.

The new regime exceeds Canada’s trade commitments under NAFTA and TRIPS. The US is Canada’s largest export market for generic pharmaceuticals, and Canadian generic manufacturers are now at a distinct competitive disadvantage vis-à-vis their US competitors who are subject to just 5 years of data exclusivity.

This increased ban on competition will worsen the problem of soaring prescription drug costs in Canada by adding more than \$100-million per year to Canada’s prescription drug bill. In November 2006, Canada’s generic pharmaceutical industry launched legal action in the Federal Court of Canada to challenge the October 2006 changes to federal regulations that provide brand-name drug makers with an eight-year ban on generic competition. In November 2007, the Federal Court agreed to proceed with the case.

Subsequent Entry Biologics

Today there are only brand-name biologics on the market in Canada. A number of biologics will be coming off-patent over the next 5 years, and the patents for others have already expired. Health Canada recently issued draft guidance for the approval of subsequent entry biologics (as generic biologics are known in Canada) and has scheduled consultations for June 2008. CGPA is committed to working with Health Canada officials to develop an effective pathway for the timely approval of safe and affordable subsequent entry biologics.

Canada’s generic pharmaceutical companies have the technological capability to develop and produce many of these biologic molecules, and are looking to establish Canada as a world leader in the development of subsequent entry biologics. For the Canadian marketplace, the introduction of subsequent entry biologics would create competition, reduce health-care costs, and increase consumer access to affordable medicines. The development of a domestic subsequent entry biologics industry would also expand the technological capacity of Canada’s world-class generic pharmaceutical industry and lead to increased investments in highly-skilled jobs, manufacturing, and research and development.

The prospects for a subsequent entry biologics industry in Canada are promising. Drugs produced from biological materials are generally more expensive to produce than small molecule drugs developed from chemical compounds, and significant research time and dollars will be invested by generic manufacturers in the creation of a single subsequent entry biologic. Market exclusivity periods for brand-name biologics must not be used to stretch patents into unfair and indefinite product monopolies. A mechanism must also be developed to ensure any patent disputes are resolved in a timely manner.

Recommendations

The Government of Canada has increased market monopolies for brand-name drug companies several times over the past 21 years (C-22 in 1987, C-91 in 1992, S-17 in 2001), but this has not resulted in more research and development spending in Canada as a percentage of sales. In fact, historical data from the PMPRB shows that the opposite is true.

Canadians would be better served through increased competition from Canada's robust generic pharmaceutical industry, which can be achieved by bringing Canada's intellectual property regime for pharmaceuticals back in line with our international trade obligations. All stakeholders would benefit from clearer rules and practices in intellectual property in the pharmaceutical and biologic sectors.

Beyond the improvements to Canada's intellectual property regime for pharmaceuticals outlined by CGPA in this short submission, other significant changes are also needed to create more certain and timely market access for generic pharmaceutical products. These include an appropriate and stable resource allocation for Health Canada regulatory programs to enable the department to meet its own review targets for generic drug products, and the recognition of Health Canada generic product approvals as the basis for national interchangeability on provincial drug formularies by all provinces.

Recommendation #1: Data Exclusivity

The *Food and Drugs Act Regulations* should be amended to reduce the period of data exclusivity for brand-name pharmaceutical companies operating in Canada from 8 years to 5 years. This change is consistent with our international trade obligations through NAFTA and TRIPS, and would remove a distinct competitive disadvantage Canadian generic manufacturers face vis-à-vis their U.S. competitors who are subject to just 5 years of data exclusivity. It would also ensure Canadians receive more timely access to less expensive generic drugs.

Recommendation #2: Patented Medicines (Notice of Compliance) Regulations

The pre-October 2006 wording of Section 8 of the *NOC Regulations* should be restored in order to discourage abuse of the automatic stay provision. Cases under the *Regulations* can cost generic manufacturers millions of dollars to litigate, and generic manufacturers should once again have the option to claim either its own out-of-pocket damages or elect an accounting of the brand-name company's profits during the wrongful delay.

Recommendation #3: Export Exception under the Patent Act

Domestic patent protection is preventing the export of Canadian-made pharmaceutical products to jurisdictions where patents are not in effect – including our largest trading partner, the United States. Patents are filed in individual countries, and expire at different times. It is crucial for Canadian generic pharmaceutical companies to be able to access international markets as soon as they open up, and domestic law is hampering the industry's expansion in legitimate export markets. It should be noted that generic drugs produced through an export exception would never be sold in Canada prior to the expiration of domestic patent protection as Health Canada does not grant a license for the products to be sold in Canada until the Canadian patent has expired.

Recommendation #4: Subsequent Entry Biologics

In order to support the development of a domestic subsequent entry biologics industry and to ensure the timely availability of these lower-cost products to Canadians, a clear approval pathway including reasonable intellectual property rules must be developed that are free from potential abuse and extension by brand-name biologic companies.