Submission to the
Standing Committee on Finance

Pre-Budget Consultations

Canadian Generic Pharmaceutical Association

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Executive Summary

The generic pharmaceutical industry is highly competitive and is the growth industry within the global life sciences sector. Canada is well positioned to build on the existing strength of its generic pharmaceutical infrastructure, but there are several uncertainties that are putting the long-term sustainability of generic R&D and manufacturing investments at risk.

These uncertainties can be addressed through the following recommendations of the Canadian Generic Pharmaceutical Association:

1. Ensure the comprehensive economic and trade agreement (CETA) between Canada and the European Union does not include the EU's proposed extensions to pharmaceutical patent monopolies. These proposals would have the effect of increasing prescription drug costs in Canada by almost $3 billion annually and delaying the availability of low-cost generic medications by an average of 3.5 years.

2. Improve the *Patented Medicines (Notice of Compliance) Regulations* to increase business certainty and ensure more efficient use of court resources. Specifically, the generic pharmaceutical industry asks the Government of Canada to:

a) end the ability of pharmaceutical patentees to initiate multiple litigations on the same patent(s) against a generic company; and

b) include safeguards that would deter pharmaceutical patentees from bringing forward frivolous cases to obtain the extraordinary 24-month automatic stay that is available under these *Regulations*, including the provision of full damages to a generic pharmaceutical company that is found to be unjustly kept off the market by the courts.

3. Ensure resources for review programs at Health Canada's Therapeutic Products Directorate are not negatively impacted by the Government of Canada's Strategic and Operating Review in order to support the successful implementation of the revised cost recovery framework implemented in April 2011, in accordance with the requirements of the *Cost Recovery Act*.

Introduction

On behalf of the Canadian Generic Pharmaceutical Association (CGPA), we are pleased to participate in the pre-budget consultation process and contribute to the House of Commons Standing Committee on Finance’s efforts to ensure a sustained economic recovery in Canada, create quality sustainable jobs, ensure relatively low rates of taxation, and achieve a balanced budget.

CGPA is the national association representing more than 11,000 Canadians who work for leading generic pharmaceutical companies based primarily in Toronto, Montreal and Winnipeg. Virtually all of the pharmaceutical manufacturing that exists in Canada is operated by generic drug companies, and vast majority of these jobs are highly-skilled research, development and manufacturing positions.

CGPA member companies invest hundreds of millions of dollars in research and development each year. Generic drug maker Apotex is the single largest pharmaceutical R&D spender in Canada and in the provinces of Ontario and Manitoba, while generic drug maker Pharmascience is the largest pharmaceutical R&D spender in Quebec.

The generic industry is globally-focused, and currently exports more than 40% of domestic production to 115 countries around the world with the United States forming our single largest export market. The generic industry is the growth area in the international life sciences sector, and Canada continues to benefit from significant foreign direct investment and domestic investment in Canadian generic pharmaceutical facilities.

Most recently Teva, the largest generic pharmaceutical company in the world, announced in July 2011 a $56 million expansion of its High Potency Manufacturing Centre of Excellence in Stouffville, Ontario. In May 2011, privately held Canadian generic pharmaceutical company Pharmascience announced at $38 million investment to increase manufacturing capacity and build new laboratories in Montreal.

In addition to the industrial benefits provided to Canada by the generic pharmaceutical industry, the use of low-cost generic medicines saved the Canadian health care system more than $7 billion dollars 2010 alone. Generic drugs are dispensed to fill 58% of all prescriptions in Canada yet account for only 26% of the $22 billion Canadians spend annually on prescription medicines.

The economic downturn and strength of the Canadian dollar has posed a significant challenge for Canadian manufacturers across all sectors. The generic pharmaceutical industry's ability to continue its significant contributions to the Canadian economy and health care system is a result of the growing demand for our products in domestic and export markets, and the efficiency and sophistication of our Canadian facilities and operations.

CGPA applauded the Government of Canada's decision to make manufacturing a priority in Federal Budget 2011 by extending the Accelerated Capital Cost Allowance by two years to include eligible assets acquired before 2014. Introduced in 2007, the two-year straight-line depreciation for investments in manufacturing and processing machinery and equipment has served to encourage investment in assets to improve productivity throughout the manufacturing sector. The extension of the Accelerated Capital Cost Allowance will support Canada's economic recovery and help Canadian generic manufacturers invest in technologies to increase productivity, strengthen competitiveness and expand into new export markets.

The Scientific Research and Experimental Development (SR&ED) Tax Credit has also proven to be an important incentive to encourage domestic research and development investments, and the continuation of this program is supported by Canada's generic pharmaceutical industry.

The generic pharmaceutical industry is highly competitive and is the growth industry within the global life sciences sector. Canada is well positioned to build on the existing strength of its generic pharmaceutical infrastructure, but there are several uncertainties that are putting the long-term sustainability of generic pharmaceutical R&D and manufacturing investments at risk. These uncertainties and CGPA's recommendations are outlined in detail below

1. Ensure the Comprehensive Economic and Trade Agreement (CETA) Between Canada and the EU Does Not Include the EU Proposals to Further Extend Pharmaceutical Patent Monopolies

The generic pharmaceutical industry is globally focused, strong proponents for enhanced trade, and supportive of the Government of Canada's efforts to eliminate trade barriers for Canadian companies. We also recognize the Government of Canada's efforts to improve intellectual property protection (IP) in some areas, particularly with respect to the current copyright reform initiatives.

Intellectual property for pharmaceuticals, however, is different from all other forms of intellectual property – both in terms of the extensive mechanisms provided to patentees and in terms of the attention it has received by domestic policy makers over the past 25 years. Canada has implemented no fewer than eight increases in pharmaceutical intellectual property measures since 1988.

The European Union, at the behest of the brand-name pharmaceutical industry, has tabled a series of proposals aimed at once again increasing market exclusivity for brand-name drug companies in Canada, many of which are headquartered in Europe and do not conduct new product development in Canada.

Canada should reject the EU's proposals for several reasons:

- The proposals are unnecessary. Canada is already home to one of the most aggressive and robust pharmaceutical IP regimes in the world, and in many ways provides stronger protection than the EU and the US.[1]

[1]Innovation for a Better Tomorrow: A Critique. Professor Edward Iacobucci, Osler Chair in Business Law, University of Toronto, May 2011. Available online at: http://www.canadiangenerics.ca/en/news/docs/05.30.11%20Innovation%20for%20a%20Better%20Tomorrow%20-%20A%20Critique_FINAL.pdf

- The EU proposals would increase the cost of prescription drugs in Canada by almost $3 billion annually and delay the availability of low-cost generic medicines by an average of 3.5 years.[2]

- The provinces would shoulder much of this financial burden through increased costs to their public drug benefit programs, and many oppose the EU's pharmaceutical IP proposals. The estimated cost to public drug benefit programs by province is as follows:[3]

Public Drug Plan	Estimated Annual Cost Increase – EU Proposals
British Columbia	$101.2 million
Alberta	$96.1 million
Saskatchewan	$40.3 million
Manitoba	$38.0 million
Ontario	$551.2 million
Quebec	$412.2 million
New Brunswick	$18.4 million
Nova Scotia	$30.0 million
Prince Edward Island	$3.4 million
Newfoundland and Labrador	$13.2 million
Northwest Territories	$1.3 million
Yukon Territory	$1.1 million

- The Government of Canada is the third largest payer for prescription drugs in Canada, and the proposals would increase the federal government's prescription drugs expenditure by approximately $150 million annually.

  - The increased cost to federal drug benefits for Aboriginal Canadians, veterans, members of the military and the RCMP, prisoners in federal correctional facilities and refugees is estimated at $83 million annually.

  - The increased cost to the Government of Canada for drug benefits payable to employees and their dependents is estimated at $66 million annually.

- Canadian employers and consumers would directly shoulder the remaining $1.5 billion cost of the proposals.

- If implemented, the proposals would lead to a significant weakening and retraction of the generic pharmaceutical industry in Canada over time as Canadian manufacturers will become less competitive on the global stage and will be unable to attract new R&D and production mandates.

- As history has shown, increasing intellectual property for pharmaceutical patentees is unlikely to lead to any significant increases in domestic R&D by brand-name drug companies.[4]

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[2] The Canada-European Union Economic and Trade Agreement: An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions. Professor Aidan Hollis, University of Calgary and Professor Paul Grootendorst, University of Toronto, February 2011. Available online at: http://www.canadiangenerics.ca/en/news/docs/02.07.11CETAEconomicImpactAssessment-FinalEnglish11.pdf

[3] Ibid.

[4] The Real Story Behind R&D Spending by Brand-Name Drug Companies in Canada, CGPA, June 2011. Available online at:. http://www.canadiangenerics.ca/en/news/docs/TheRealStory2011.pdf

Recommendation #1:

There are currently no barriers to trade in pharmaceuticals between Canada and the European Union. The EU proposals are unnecessary and would be costly for Canadians if implemented. Canada has the ability to negotiate an ambitious CETA with the European Union without succumbing to the EU's proposals to increase market monopolies for pharmaceuticals.

2. Improve the *Patented Medicines (Notice of Compliance) Regulations* to Increase Business Certainty and Ensure More Efficient Use of Court Resources

The Canadian IP regime for pharmaceuticals links the approval of a generic medicine to the existence of patents on a register. This is called a "patent linkage" system. It provides a brand-name company with the ability to block the entry of generic competitors by way of an automatic injunction without any upfront burden of proof. Such a system is uncommon outside of North America, and the Canadian patent linkage system operates in a very different manner than the U.S. patent linkage system.

In well over two-thirds of cases brought under the *Regulations*, the brand's patent concerns ultimately prove to be without foundation: the courts find the patents to be invalid or not infringed by the generic product. The generic product is often wrongfully kept off the market for years in this way.

The two problems with the *Regulations* that require urgent attention:

(a) The lack of an adequate damages provision in the *Regulations*.

It has become clear in the courts that if a generic market entry is wrongfully delayed under the *Regulations*, the manufacturer either cannot obtain damages from the brand company, or may at best be entitled to recover only a fraction of its actual business loss. Not a single damage award has been granted under the damages provision (section 8) since the *Regulations* first came into force in 1993.

A 24-month automatic stay is a powerful tool for pharmaceutical patentees in Canada, and is not available to patentees in any other sector. There are currently no safeguards to discourage pharmaceutical patentees from initiating frivolous cases in an effort to extend patent monopolies. In fact, the opposite is true. There is no down side for brand-name drug companies to initiate litigation on patents that are either weak or would not be infringed. The potential damages they would pay under the current *Regulations* are far outweighed by the profits made through longer periods of market monopoly even if they ultimately lose the court case. As such, there is a proliferation of such cases consuming court resources and generic companies win 70% of decided cases under the *Regulations*.

Generic manufacturers investment millions of dollars in their efforts to bring a new generic product to market, and should be able to claim full compensation against a brand-name company when unjustly kept off the market by way of the extraordinary 24-month automatic stay.

(b) A court decision under the *Regulations* does not resolve the patent dispute.

No other country forces generic manufacturers to engage in litigation which does not resolve the patent issue, as Canada does. In Canada's system, a generic manufacturer that litigates for years and wins under the *Regulations* can still be sued again on the same patent under the *Patent Act* by the same brand company as soon as it enters the market.

Allowing multiple sets of separate litigation on the same patent or set of patent(s) is extraordinary under any modern legal system.

The generic manufacturer therefore enters the market at risk that it could be found liable for all the brand-name company's lost profits, an amount many times larger than any profit it could possibly earn from its low-cost generic product that is sold in a multi-source environment.

If litigation under the *Regulations* does not resolve the patent dispute, and the generic manufacturer loses when the patent is litigated a second time under the *Patent Act*, its liability could be so large that bankruptcy is conceivable, in the case of a major drug. It is obviously difficult for a rational business to justifying investing in the development of new products in these circumstances. The system also incentivizes brand companies to litigate against and delay all generic drugs, even if they know their patents are invalid or not infringed.

If patents are to be challenged successfully, and generic products brought to market at the earliest appropriate time, the *Regulations* are urgently in need of revision. If a brand-name company elects to commence litigation under the *Regulations,* automatically keeping the generic product off the market, but is unsuccessful on the patent issues, it should compensate the generic manufacturer in damages for *all* harm to its business resulting from the wrongful stay, at whatever stage of the litigation the stay is lifted.

Recommendation #2:

In order to increase business certainty, limit undue cost and risk exposure, and ensure better use of court resources, the Government of Canada should seek to amend these *Regulations* to:

- End the practice of allowing multiple litigations on the same pharmaceutical patent(s) against a generic pharmaceutical company; and

- Create safeguards to deter patentees from bringing forward frivolous cases, and ensure courts have the ability to award full damages when the extraordinary 24-month automatic stay available to patentees under the *Regulations* is misused or abused.

3. Ensure Resourcing of Regulatory Programs Operated by the Therapeutic Products Directorate Can Proceed

Health Canada regulatory programs serve as the gatekeepers to commercializing the prescription drug products that Canadians demand. These programs can either discourage commercialization, or they can facilitate and encourage it.

Pharmaceuticals are among the most highly-regulated products in Canada. Regulatory delays can have significant business implications and can contribute to the possibility of a drug shortage.

The Therapeutic Products Directorate of Health Canada has had significant challenges in meeting their own internationally competitive performance targets for review programs for many years. Several initiatives aimed at creating process efficiencies have been explored by the directorate over the years, but this has not addressed the chronic problem of an insufficient number of review staff to manage increasing workloads.

With the implementation of a new cost recovery framework for therapeutic programs by the Health Products and Food Branch effective April 2011, the Directorate is now in the process of hiring and training new resources with the goal of improving regulatory performance and meeting the requirements of the *Cost Recovery Act*.

Recommendation #3:

Ensure resources for review programs at Health Canada's Therapeutic Products Directorate are not negatively impacted by the Government of Canada's Strategic and Operating Review in order to support the successful implementation of the revised cost recovery framework implemented in April 2011, in accordance with the requirements of the *Cost Recovery Act*.