

EU Pharmaceutical Intellectual Property Proposals  
in the Negotiations for a Comprehensive Economic  
and Trade Agreement (CETA)

## **Potential Impact on the Generic Pharmaceutical Industry in Canada**

October 11, 2011

*A study commissioned by the Canadian Generic Pharmaceutical Association*

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## Abstract

*Canada's generic pharmaceutical industry is a rapidly growing R&D, manufacturing and export-intensive industry that provides a positive contribution to the Canadian society in terms of both the cost of prescription drugs and industrial benefits. In fact, the generic industry in Canada now has almost the same size (e.g. employment levels) as the brand-name pharmaceutical industry.*

*Proposals made by the European Union in the current negotiations for a Comprehensive Economic and Trade Agreement (CETA) with Canada would extend Canada's intellectual property protection for pharmaceuticals by an average of 3.5 years. These Proposals include extended patent periods, extended data protection and a regulatory right of appeal for brand companies in addition to the existing appeal rights under the Patent Act.*

*According to generic pharmaceutical industry executives, the implementation of these Proposals would cause a 20% to 30% overall decline in industrial activity by generic pharmaceutical companies in Canada compared to current levels in the short to medium term. The resulting delay in market entry would significantly diminish industry incentives to invest in the development of new generic drugs. The prospect of using Canada as a major global production and export base, which is currently the case for several companies, will also be impacted. Production and R&D mandates would ultimately be diverted to other jurisdictions.*

*Canada will have lost an opportunity to maintain a diversified life science industry as well as the resulting benefits in terms of employment, public finances and international trade.*

# Executive Summary

Canada's generic pharmaceutical industry has a strong industrial base centred in the Montreal, Toronto and Winnipeg regions, and employs more than 11,000 Canadians in highly skilled R&D and manufacturing positions. In addition to producing most of the generic drugs sold in the domestic market, generic products manufactured in Canadian facilities are exported to more than 115 countries around the globe. The value of these low-cost exported products exceeds more than \$1 billion annually.

The global demand for generic pharmaceuticals is growing at a rate of 10 percent each year, and the global market is expected to grow to \$358 billion by 2016. Canada is currently well positioned to benefit from the global growth of this industry through existing generic pharmaceutical R&D and manufacturing facility investments by several global companies and Canadian-based companies, as well as the infrastructure expansions announced earlier this year.

Canada currently has an intellectual property regime for pharmaceuticals that exceeds our international trade obligations, and is in many ways stronger than the European Union (EU) and the United States. Even so, the EU has tabled several proposed changes to Canada's intellectual property regime for pharmaceuticals in the current negotiations for a Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union aimed at delaying the availability of new generic drugs by an average of 3.5 years and adding \$2.8 billion annually to Canada's prescription drug bill. These increased costs would be paid by private and public sector payers, consumers and taxpayers.

The EU proposals would have impacts beyond health care expenditures. This analysis focuses on the impact of the EU Proposals on Canada's generic pharmaceutical industry.

## 1. Short to medium term impact

If the EU Proposals are adopted, Canadian generic pharmaceutical industry could face reduced market potential and investment. According to interviews with industry executives, an average decline in generic pharmaceutical industrial activity of 20% to 30% could be expected. The impact could be even more severe for some generic companies.

Canadian generic pharmaceutical companies would lose export markets and manufacturing mandates for new generic molecules. As a result, some R&D projects already under way would be abandoned. There would also be less R&D on new molecules in the future as securing future project financing would be more difficult in the competitive global environment. Production of older molecules will likely continue, but dependence on existing products will diminish the revenues of

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The question is whether future investments by the generic pharmaceutical industry in Canada can be justified to maintain, let alone expand, R&D and manufacturing capabilities.  
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Canadian companies. Reduced upgrades of existing manufacturing and R&D centers could be expected. The lower revenues, later market entry and reduced ability to compete for global mandates will also provide less incentive for generic companies in Canada to challenge weak and frivolous patents.

## **2. Long term impact**

If the EU Proposals are adopted, the generic pharmaceutical industry would face a highly uncertain presence in Canada. Companies are expected to divert production and R&D mandates to industrial facilities in other countries that present a more attractive investment climate. Shutdowns and relocations are possible, resulting in job losses to the industry and its suppliers. Ultimately, only commercial activities (import and distribution) would likely remain.

### **Key Findings**

If the EU Proposals are adopted, Canada could face the loss of a profitable, R&D-intensive and fast-growing industry. Generic pharmaceutical companies in Canada would lose their ability to seek timely access to new export markets, and opportunities in foreign markets would be captured earlier by manufacturers in countries that do not have the comparable barriers to trade that the EU Proposals would create.

The industry will have lost its capacity to contribute to Canada's economy and public finances. Canada will lose the ability to capture the benefits of a worldwide growth industry. Ultimately, the private and public sector payers, consumers and taxpayers would pay the price.

# Introduction

## Context

Canada is home to an internationally significant cluster of generic pharmaceutical manufacturers, based primarily in Ontario and Quebec. The industry employs more than 11,000 Canadians and manufactures most of the generic drugs sold in Canada. By way of comparison, the brand-name industry employs 13,000 workers in Canada<sup>1</sup>.

Several hundred million dollars are spent each year in the development of new generic molecules. The generic pharmaceutical industry is also globally-focused, and exports 40% of Canadian production to more than 115 countries.

Canada and the European Union (EU) are currently engaged in negotiations for a Comprehensive Economic and Trade Agreement (CETA), and the EU is asking Canada to review its intellectual property regime as it applies to pharmaceutical products. Of specific concern to generic pharmaceutical firms are the following Proposals that provide one-sided advantages to the brand industry:

- **Supplementary Protection Certificates**, intended to add up to 5.5 years to a standard and internationally-accepted patent period of 20 years.
- A **Right of Appeal** under Canada's patent linkage regime, which ignores their existing appeal rights under the Patent Act.
- An **increase in the length of Canada's data protection regime** of up to 2.5 years and expanded scope for what qualifies for data protection, which ignores the fact that Canadian data protection far exceeds most countries.

The future prospects for the generic pharmaceutical industry in Canada would be negatively impacted should these Proposals be adopted.

## Objective

A separate analysis focused on the impact that the EU Proposals would have on the cost of prescription drugs in Canada has already been completed<sup>2</sup>. The current analysis focuses on the impact of the EU CETA Proposals on Canada's generic pharmaceutical industry and on the Canadian economy.

<sup>1</sup> PricewaterhouseCoopers. *The Québec-Ontario Life Science Corridor, Combining Strengths, Maximizing Impacts* – 2011.

<sup>2</sup> Aidan Hollis, Professor, Department of Economics, University of Calgary and Paul Grootendorst, Associate Professor, Faculty of Pharmacy, University of Toronto, *The Canada-European Union Comprehensive Economic & Trade Agreement – An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions*, February 2011.

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What would be the impact of the changes to Canada's intellectual property rules demanded by the European Union on Canada's generic pharmaceutical industry?

This is the question that this study seeks to address.

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This study is based  
on in-depth  
interviews with  
executives of  
companies  
representing more  
than 90% of the  
generic industry's  
revenues in  
Canada.  
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While the economic contribution of the generic pharmaceutical industry in Canada has generally been considered in terms of advantages to the Canadian payers and consumers, relatively little attention has been paid to the economic contribution of this industry in terms of employment, taxes and exports. In fact, little to no economic information is available from government sources, such as Statistics Canada. Despite significant capital investments and export activity over the past decade, the generic pharmaceutical industry has kept a low profile about its contributions. The purpose of this study is to examine if and to what extent the EU Proposals may jeopardize these continued economic contributions.

This study is based on in-depth interviews with leading executives of generic pharmaceutical companies who represent more than 90% of the industry's revenues in Canada, and other documented sources.

#### Document Structure

Section 1 provides a profile of the generic pharmaceutical industry and its prospects for development in Canada and abroad. Section 2 describes the industrial environment and decision-making process characterizing the generic firms in Canada, as well as Canada's international positioning in terms of investment climate for generic pharmaceutical industrial investments. Section 3 examines the impact of the EU Proposals on Canada's generic pharmaceutical industry.

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**E&B (Economic & Business) Data** is an independent privately-owned economic consulting firm. It is specialized in industrial investment analysis, including economic impact analysis, site selection and investment incentive program review. Its clients include international investors, industrial associations, government agencies and trade unions. It operates in North and South America and overseas. **Octane Strategies**, a strategic communication firm with extensive expertise in the Canadian generic pharmaceutical industry, provided support to E&B Data in the preparation of this study.



# 1. The Generic Pharmaceutical Industry: Current Situation in Canada and International Outlook

The importance of the generic pharmaceutical industry in Canada and its prospects for growth are generally not well known. This section presents an overview of the Canadian generic pharmaceutical industry and its growth prospects in the international market.

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In 2011, the use of generic drugs is expected to save the Canadian health care system more than \$7 billion.  
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## 1.1 Basic Facts and Figures

Prescription drug expenditures in Canada reached \$26 billion<sup>3</sup> in 2010, 46% of which were incurred by the public sector. With the average age of the population increasing, the share of the cost of medication paid by the public sector will also increase as retirees gradually leave private sector coverage. As well, the total amount spent on prescription drugs will increase due to the aging population.

### 1.1.1 Contribution to Health Care

The generic pharmaceutical industry makes significant contributions to the control of health care costs in Canada. Domestic generic prescription pharmaceutical sales reached \$5.7 billion in 2010, representing 26% of the total domestic expenditure on prescription pharmaceuticals and accounting for more than 57% of the total number of prescriptions filled<sup>4</sup>. Indeed, the average retail price for a patented drug prescription is approximately 2.6 times higher than the bioequivalent generic drug. In 2011, the use of generic pharmaceuticals is expected to save the Canadian health care system more than \$7 billion<sup>5</sup>.

### 1.1.2 Contribution to the Economy

In terms of its contribution to the Canadian economy:

- **Employment:** The generic pharmaceutical industry provides direct employment to 11,000 workers in Ontario and Quebec<sup>5</sup>, offering well-paid, highly skilled jobs in research and development, production and operations. This figure does not take into account approximately 150 jobs

<sup>3</sup> Canadian Institute for Health Information. *Drug Expenditure in Canada, 1985 to 2010*. May 5, 2011.

<sup>4</sup> IMS Health, March 2011.

<sup>5</sup> Canadian Generic Pharmaceutical Association. *The Value of Generic Prescription Medicines. Are you taking full advantage?* June 2011.

in other provinces and indirect jobs created by suppliers and partners in Canada.

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The Canadian generic pharmaceutical industry directly employs 11,000 Canadians. Over the past decade, it has invested more than \$1.5 billion in manufacturing and R&D centers with limited government financial support.

- **Investments:** Capital investment projects whose overall value exceeds \$1.5 billion have been undertaken since 2000 for manufacturing and R&D facilities in Canada<sup>6</sup> with limited financial support from government. This amount does not include the ongoing R&D expenditures of Canadian generic pharmaceutical firms.
- **R&D:** Generic pharmaceutical companies operate 12 R&D laboratories in Canada. These facilities are focused on developing and perfecting formulas, improving ways of administering pharmaceuticals, and finding solutions to increase patient compliance with their therapies. The industry operates several other laboratories focused on quality assurance. Generic pharmaceutical companies are major R&D spenders in Canada, investing several hundred million dollars annually. Generic drug-maker Apotex is the single largest R&D spender in the life sciences sector in Ontario and Canada, investing close to \$200 million in R&D in 2010<sup>7</sup>. Generic drug-maker Pharmascience is the single largest life sciences R&D spender in Quebec<sup>7</sup>. Competitiveness and the continued globalization of the industry is reflected in the activities of generic pharmaceutical companies in Canada, where more than half of Canadian R&D investments are related to international export markets<sup>8</sup>.
- **Exports:** Canada's generic pharmaceutical industry is actively involved in international trading. Its international competitiveness has allowed it to be a strong exporter, thus contributing positively to Canada's balance of trade in pharmaceuticals. Indeed, 40% of its domestic production is exported to more than 115 countries worldwide<sup>8</sup>, with approximately 75% of exports destined for the United States. The value of Canadian generic pharmaceutical exports exceeds \$1 billion per year.
- **Taxes:** The generic pharmaceutical industry contributes approximately \$250 million in direct tax payments every year<sup>9</sup>. This contribution to government revenues does not include other contributions (e.g. personal income taxes) paid by direct and indirect workers<sup>10</sup>.

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The generic pharmaceutical industry contributes more than \$250 million in direct taxes every year.

<sup>6</sup> Interviews with industry.

<sup>7</sup> InfoSource. *Top Corporate R&D Spenders*. 2010.

<sup>8</sup> Interviews with industry.

<sup>9</sup> Canadian Generic Pharmaceutical Association survey of member companies.

<sup>10</sup> i.e. those employed by the industry's suppliers' network in Canada.

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 No matter where  
 their headquarters  
 are based, all  
 generic  
 pharmaceutical  
 firms operating in  
 Canada are now  
 globalized.  
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## 1.2 The Industry Players

While most patented pharmaceuticals sold in Canada are imported, the majority of generic pharmaceuticals sold in Canada are manufactured in Canada. The major generic pharmaceutical industry players in Canada are noted below according to market share.

**Figure 1. Ranking of Generic Pharmaceutical Companies in Canada (Based on sales in hospitals and pharmacies in Canada)**

Companies	2010 (\$ millions )	Market share
Teva Canada*	1,597	28%
Apotex Inc.	1,355	24%
Pharmascience	583	10%
Sandoz*	466	8%
Mylan*	438	8%
Cobalt Pharma (Watson)*	313	5%
Ranbaxy (Daiichi Sanyo)*	210	4%
ProDoc	139	2%
Hospira*	83	1%
Taro (Sun Pharmaceuticals)*	51	1%
Others	473	8%
<b>Total</b>	<b>5,708</b>	<b>100%</b>

\*Foreign-based companies

Source: IMS Health Canada

Several of Canada's main suppliers of generic pharmaceuticals have plants in Canada, including:

- Foreign-owned firms which rank among the world's top ten generic pharmaceutical firms;
- Canadian-owned firms (Apotex and Pharmascience) which are Canada's second and third ranked generic companies in terms of sales. They are also the only two Canadian-owned multinationals in the pharmaceutical sector (brand-name and generic industries combined).

The presence of these national and international leaders, and the availability of skilled labour led to the establishment or acquisition of manufacturing plants and R&D centres by foreign-owned companies seeking to use Canada as a base for their North American development.

Canada therefore benefits from the presence of both manufacturing and R&D operations. This is not usually the case in other industries, where R&D is often located in close proximity to international headquarters. Indeed, generic products are typically manufactured in the countries where they have undergone a thorough

R&D process in formulation and testing, which typically takes between three and six years.

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Generic pharmaceutical companies have a strong presence in Ontario and Quebec, where more than 95% of their research and manufacturing activities are now concentrated.

### 1.3 Geographical Presence

The generic pharmaceutical industry has had a strong presence in Canada since the 1950s. More than 95% of the industry's research and manufacturing activities are now concentrated in Ontario and Quebec.

- In Ontario, Teva, Taro and Apotex operate several manufacturing and R&D facilities. Ontario has a total of seven laboratories devoted to the development of new generic molecules. Apotex has 2,000 scientific staff engaged exclusively in new generic molecule research and development. As part of its global manufacturing capacity, Teva operates North America's largest penicillin plant in Markham. Teva's Centre of Excellence for Solid Dose Products in Stouffville produces 400 different formulations, primarily for the North American market. Apotex has 20 facilities, primarily in Ontario, and has the capacity to produce 1.2 billion capsules and tablets per month. Apotex produces more than 300 generic pharmaceuticals in approximately 4,000 dosages and formats in Canada. Taro's facility in Brampton specializes in the production of dermatology medications, and almost all of the creams, ointments and gels sold by Taro worldwide are manufactured in this facility.
- In Quebec, Pharmascience, with 1,300 employees in Montreal (to increase to 1,500 after the completion of a major investment announced in May 2011) is now the largest life sciences company in the province. Sandoz Canada, with 800 employees in Boucherville, is also one of the largest employers in Canada's life sciences sector and is a worldwide centre of excellence for the research, development and manufacture of injectable products within the Sandoz Group<sup>11</sup>.

Although the vast majority of activities are concentrated in Quebec and Ontario, Apotex also operates multiple facilities in Manitoba, which represents the largest life science investment in that province.

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<sup>11</sup> The most recent manpower survey conducted by Pharmabio Développement confirms the importance of these companies to the Quebec economy: the major employers in the pharmaceutical and biotechnology sector are generic pharmaceutical firms. *Résultats – Enquête main d'œuvre 2010*, Pharmabio Développement (Comité sectoriel de la main d'œuvre des industries pharmaceutiques et biotechnologiques), Commission des partenaires du marché du travail du gouvernement du Québec

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The significant drop in the number of new innovative molecules being developed is changing the growth pattern of the pharmaceutical industry worldwide.  
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## 1.4 International Growth Prospects

International developments in the pharmaceutical industry have the potential to impact Canada's generic pharmaceutical industry, whether it concerns overall market growth, the structure of industry or the level of competition. This section examines current market and industry trends that could impact global investment decisions in the generic pharmaceutical industry.

### 1.4.1 Generic Pharmaceutical Firms and Brand-Name Firms

Valued at approximately US\$850 billion in 2009<sup>12</sup>, forecasts suggest the world pharmaceutical market will exceed US\$1.3 trillion in 2020<sup>13</sup> as a result of demographic changes, the introduction of preventive treatments and the general increase in the standard of living in emerging countries. However, this growth will not equally benefit every sub-sector of the pharmaceutical industry. The life sciences sector as a whole is undergoing significant structural changes, and the generic pharmaceutical industry has become the fastest growing component of the sector. Indeed, according to IMS Health: *"The number of patents due to expire in the near future marks a growth switch to generic pharmaceuticals."*<sup>14</sup>

Whereas brand-name firms have played a key role in the past in terms of global R&D activities, their contribution in this respect had decreased considerably by the middle of the past decade. The world demand for pharmaceuticals is increasing rapidly, but public administrations and consumers cannot absorb all the financial pressures associated with the increasing cost of pharmaceuticals, especially highly-priced patented pharmaceuticals that may provide no therapeutic benefits over existing therapies. A similar concern applies to those who contribute to private prescription drug insurance plans (companies and their employees), who have seen the cost of their drug plans increase in recent years.

Manufacturers of generic pharmaceuticals help to ease those pressures by offering an alternative for providing a large-scale supply of competitively priced bioequivalent pharmaceutical products. This role is being recognized by industry stakeholders. For example, according to a member company of the Allianz Group, one the world's largest insurance companies:

*'Generics are expected to represent 17% of the [value of] global pharmaceuticals market in 2014, up from 10% in 2008. This growth, driven largely by maturing blockbuster patents in developed economies, is also stimulated by government policies that encourage*

<sup>12</sup> IMS Health. *IMS Market Prognosis 2010*, October 2009.

<sup>13</sup> PricewaterhouseCoopers. *Pharma 2020: The Vision – Which Path Will You Take?* June 2007.

<sup>14</sup> IMS Health. *IMS Market Prognosis*, April 2010.

*the prescription of generics by reimbursing them at more favourable rates than branded names*<sup>15</sup>.

With annual worldwide growth prospects estimated at 10% over the coming years<sup>16</sup>, the generic pharmaceutical industry will be a driving force in the life sciences sector as a whole.

#### **1.4.2 Competition within the Generic Pharmaceutical Industry**

The generic pharmaceutical industry is highly competitive, whether internationally or in Canada. The competitiveness of the domestic generic pharmaceutical industry has been reaffirmed by the Competition Bureau of Canada<sup>17</sup>.

The pricing and reimbursement market frameworks for generic drugs in Canada are generally set by provincial governments in Canada for both the public and private markets. Several provinces have taken measures to reduce reimbursed retail prices of generic drugs in recent years.

Declining retail prices are creating unique pressures on generic pharmaceutical firms. Due to intense competition in the generic markets, firms must work at various levels in order to remain profitable overall. This can be achieved by becoming established in emerging markets and by developing very large scale production and distribution capacities, attaining higher productivity, optimizing cost structure, and developing complementary technologies or product portfolios. Such strategies are achieved through:

- corporate realignments: the consolidation of players on the international scene, where a number of mergers and acquisitions have altered the industry structure; and on
- geographical realignments: investments have become very mobile, as investors are always seeking locations which will provide the best potential for profits.

Prospects for the profitability of Canadian operations are dependent on timely access to domestic and international markets, which in turn is largely dictated by domestic IP considerations. Unlike most other jurisdictions, the product approval process in Canada is linked to the status of patents. Health Canada is prohibited from granting health and safety approval of a generic product if there is a legal dispute between the brand and generic firm, known as a patent linkage proceeding

<sup>15</sup> Euler Hermes. *Pharmaceuticals : an Industry on the Defensive*, February 2011.

<sup>16</sup> "The global demand for generic pharmaceuticals is growing at a rate of 10 percent each year, and the global market is expected to grow to \$358 billion by 2016." BCC Research. *Generic Drugs: The Global Market*, September 2011.

<sup>17</sup> Competition Bureau Canada. *Generic Drug Sector Study*, October 2007.

Also *Benefiting from Generic Drug Competition in Canada: The Way Forward*, November 2008.

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The countries willing and able to retain and expand their existing industrial base in generic pharmaceuticals will be the ultimate beneficiaries of the worldwide long-term growth prospects for these products.  
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**Strong  
competitive forces  
within the global  
generic  
pharmaceutical  
industry compel  
companies to be  
constantly on the  
lookout for  
favourable  
environments.**

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under the *Patented Medicines (Notice of Compliance) Regulations*. In addition to being unable to access the domestic market while such proceedings are ongoing, the generic company is also prohibited from manufacturing the product for export as there is no export exception to Canada's pharmaceutical patent laws.

## 1.5 Concluding Remarks

Canada's generic pharmaceutical industry has been steadily growing as the demand for generic products has been increasing because the conditions to use Canada as an export base to supply the United States and other international markets have been generally favourable.

The continued growth of the generic pharmaceutical industry will benefit the countries in which they conduct R&D and manufacturing activities. Countries that are willing and capable of retaining and expanding their existing industrial base for generic pharmaceuticals will be the ultimate beneficiaries of the worldwide long-term growth forecast for this industry.

The next section examines the future of the generic pharmaceutical industry in Canada with respect to the Canadian investment climate and the complex global investment decision-making process of generic pharmaceutical companies.

## 2. Canada's International Positioning for New Generic Pharmaceutical Investments

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The generic pharmaceutical industry provides positive economic effects – direct, indirect and structural.

Attracting and retaining such investments depends on the compatibility or 'fit' between investors' requirements and the local investment climate.

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International industrial investment in a given country can be examined by its desirability in terms of economic impacts, and in terms of its compatibility between investors' requirements and the local investment climate. This section examines both considerations from the perspective of Canadian generic pharmaceutical executives.

### 2.1 The Economic Desirability of Investments in the Generic Pharmaceutical Industry

Capital investments for manufacturing and R&D facilities are generally desirable for Canadian society in terms of socio-economic contribution, through a combination of direct, indirect and structural impacts. This is the case for the generic pharmaceutical industry in Canada:

- Direct impacts include job creation and retention within generic pharmaceutical companies, taxes (corporate, workers' income taxes, value-added taxes) as well as contributions to Gross Domestic Product (GDP) and the balance of trade.
- Indirect impacts include jobs, taxes and GDP generated by the suppliers' networks (e.g. the suppliers of generic pharmaceutical companies, and their own suppliers) in Canada.
- Structural impacts can take a variety of forms. They can include the support for higher education networks (e.g. through grants and joint R&D projects with universities), and the development of expertise and skills (e.g. through certifications) that are transferable to other industries. They may also have a stabilizing effect on a large industry group (e.g. life science industry), when one or the other of its components faces a downturn.

For these reasons, many countries (and their states/provinces) allocate resources to attract these internationally mobile investments. They typically target high growth industries, since firms within these industries are always seeking the most strategically advantageous countries in which to locate their new facilities. Since the international business promotion and attraction process requires dedicated organizational and financial efforts, many countries prioritize the maintenance of their existing industrial base and provide the conditions to facilitate its expansion.



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The presence of a financially healthy generic pharmaceutical industry may help stabilize the entire pharmaceutical industry in Canada.  
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The generic pharmaceutical industry is a good candidate for industrial development by countries that wish to attract and retain its industrial activity. As discussed in Section 1, the world demand for generic pharmaceuticals is increasing by more than 10% per year and will continue to increase on a long-term basis due to an aging population worldwide, the increased affluence of consumers in BRIC (Brazil, Russia, India, China) and other developing countries, and the increasingly urgent need for public administrations to control health care expenditures. Based on these fundamental considerations, generic pharmaceutical investors are preparing for future growth through international mergers and acquisitions, as well as through capital investments in new manufacturing and R&D operations<sup>18</sup>. All generic pharmaceutical firms in Canada also have branches and partners in other countries. Most of them have R&D and manufacturing operations abroad and all actively invest in their operations.

For these reasons, the generic pharmaceutical industry investments should be pursued for their ongoing contributions to the Canadian economy. The economic contributions of the generic pharmaceutical industry are especially desirable given the challenges faced by other sectors of the life science industry, namely:

- the dearth of new pharmaceutical discoveries which is deeply affecting the brand-name pharmaceutical firms' profitability, employment level and investment plans, and
- the financial difficulties of many biotechnology firms, such as challenges in securing upfront capital. The presence of a financially healthy generic pharmaceutical industry may help stabilize the entire pharmaceutical industry in Canada (e.g. export levels, integration of laid-off workers in other sub-sectors of the industry)<sup>19</sup>.

## 2.2 Generic Investor Decision-Making Process

The investment climate of a given country can be defined in terms of how attractive or unattractive it is perceived by potential international investors who have site selection decisions to make between locations in various countries, whether for manufacturing or R&D centers. It is the sum of a given country's performance based on a series of location criteria or factors<sup>20</sup>. For the generic

<sup>18</sup> Numerous mergers and acquisitions have involved smaller firms operating in single countries, and the remaining national firms typically feel the need to internationalize. Expanding on the home-ground is no longer inevitable, since options now exist; investment decisions now involve balancing the various advantages and disadvantages of locating in country A versus country B.

<sup>19</sup> Keeping a healthy high technology industry such as the life science industry in Canada is all the more important as there are questions regarding the sustainability of the current expansion in natural resources projects. Industrial diversification will make Canada more resilient in the occurrence of down cycles.

<sup>20</sup> These vary considerably *between* industries (e.g. energy-intensive industries will base their locational decision very differently from computer games developers) and sometimes *within*

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The predictability or volatility of the legal and regulatory environment is a key factor in the assessment of a national investment climate.

Increasing complexity and lack of certainty of outcomes were recurring themes in interviews with generic industry executives.

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pharmaceutical industry, industry executives have identified several location factors which can be grouped in three interconnected sets: 1) market factors, 2) cost factors, and 3) the underlying legal and regulatory environment.

### **2.2.1 Market Factors**

Market factors concern the size of the current and future market, both in terms of number of prescriptions filled and net revenues. The 'market' is not necessarily limited to the national market and can include the export markets that can be accessed from the country, given its geographical proximity and/or trading arrangements.

Large industrialized countries with affluent consumers are of obvious interest to investors, as are large developing countries where there are still vast unmet supply needs and a growing base of new consumers to serve.

Countries with a smaller domestic market size may also be of interest to international investors if they provide an 'export base' from which to serve larger markets. This has been the case for Canada, which represents approximately 2% to 3% of the world market for generic pharmaceuticals and also exports domestic production to more than 115 countries.

### **2.2.2 Cost Factors**

The cost factors considered in site selection are those which are 'location-sensitive'. The cost of labour, whether related to manufacturing or R&D, is a major decision-making factor identified by generic pharmaceutical executives, especially given the wide disparities between countries. Interviews with industry executives noted a 50% and higher difference between labour costs in Canada and India<sup>21</sup>, whether for manufacturing, R&D or for clinical testing. In terms of labour productivity, Canada's advantage with respect to its skilled labour is being reduced as developing countries are rapidly closing the gap.

In terms of taxes, Canada's advantages regarding R&D are also being eroded, with some countries offering increasingly attractive tax incentives.

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industries (e.g. financial incentives will weigh more in the final decision for firms facing financial challenges than firms with a healthy balance sheet and strong cash position).

<sup>21</sup> India is of particular importance as a benchmark for investment climate assessment given its openness to outward and inward investment for generic drugs.

### 2.2.3 Legal and Regulatory Environmental Factors

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Despite its high cost environment, Canada's productivity is achieved through manufacturing flexibility, allowing companies to retool a large number of small production runs, which large-scale production plants located abroad are not equipped or skilled to handle.

The legal and regulatory environment has a direct impact on both market and cost factors. Patents and data exclusivities are such key factors, as are price controls and reimbursement policies. Another key factor is how neutral national policies may be regarding the strategies brand-name companies use in delaying the availability of generic pharmaceuticals.

As explored below, the business predictability and other advantages provided by the legal and regulatory environment are especially important to generic pharmaceutical investors. In fact, investors may opt for a country's sub-optimal but improving investment climate, over a country with a currently positive investment climate that presents negative signs or uncertainties with respect to its legal and regulatory framework.

#### Location Factors Categories and Examples of Sub-Factors

Legal and Policy Environment

- IP Protection : patents and exclusivities
- Litigation intensity
- Complexity
- Predictability
- Early entry capacity
- Export sales limitations
- Government policy coherence (e.g. IP, reimbursement)

Market Factors

- Domestic Market Size
- Forecasts(Rx, Prices)
- Export Markets
- Early Entry Potential

Location Sensitive Cost Factors

- Labour (production and R&D)
- Utilities
- Taxes
- Incentives
- Cost of submissions

## 2.3 How Countries Compete for Generic Pharmaceutical Investments

Large countries have a natural incentive and capacity to support a domestic generic pharmaceutical industry. The primary social benefits which are sought (competitive drug prices) go along with corresponding economic and industrial benefits (employment, government revenues and exports). Those countries which have a large and swiftly growing internal market with a low-cost environment have an advantage in attracting the generic industrial infrastructure. It is therefore no surprise that India has emerged with a strong and expanding generic pharmaceutical industry. Some smaller countries may also successfully position themselves to attract export-oriented generic pharmaceutical manufacturing plants. These countries typically compensate the lack of a significant internal market with strong investment incentives.

While low costs are obvious advantages to sustain a country's competitiveness in the generic pharmaceutical industry, countries with high costs can still manage to position themselves based on high productivity.

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Canadian policies are not seen as neutral, since they appear to favor one sector of the pharmaceutical industry at the expense of another.  
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- In large, high-cost countries such as the United States, such productivity is achieved through large ‘world-class’ plants providing superior economies of scale.
- For smaller markets such as Canada, such productivity is achieved through manufacturing flexibility, permitting the retooling of a large number of small production runs, which large-scale production plants located abroad are not equipped or skilled to handle.

While market size and cost levels are key factors, they can be enhanced or compensated to a large extent by appropriate domestic policies and legal/regulatory environment. For many years Canada’s Scientific Research and Experimental Development (SR&ED) tax credit program was a distinctive advantage until a similar approach was adopted by other countries competing for technological investments. In fact, other countries have added a series of distinct incentives, such as those related to job creation and reimbursement policies, which make them strong contenders to attract such global investments.

## 2.4 Canada’s Investment Climate

Several intellectual property and regulatory policies have had the effect of limiting the potential for generic pharmaceutical investments in Canada. These include:

- The ability of brand companies to obtain a 24-month automatic injunction to block generic market entry;
- The same patent or set of patents can be subjected to multiple rounds of patent infringement litigation;
- The length of regulatory data protection is one of the longest in the world;
- The lack of a statutory incentive for generic pharmaceutical companies to challenge patents;
- The ability of a brand-name company to obtain patents on multiple aspects of a pharmaceutical without any mechanism for generic companies to oppose a patent except through litigation.<sup>22</sup>

Canada already ranks in the upper tier of over 125 countries with respect to its overall IP environment<sup>23</sup> and recent statements to the contrary concerning its application in the pharmaceutical industry<sup>24</sup> have been criticized because of serious methodological limitations<sup>25</sup>.

<sup>22</sup> Edward M. Iacobucci, Osler Chair in Business Law and Professor of Law at the University of Toronto *Innovation responding to statements of the Canadian Intellectual Property Council (CIPC) for a Better Tomorrow – A Critique*, May 2011.

<sup>23</sup> Taylor Wessing Global IP Index 2011.

<sup>24</sup> *Canadian Intellectual Property Council (CIPC)* – Canadian Chamber of Commerce.

<sup>25</sup> Iacobucci. May 2011.

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The current  
business  
environment in  
Canada has up to  
now allowed  
timely entry in the  
Canadian and  
international  
market for some  
molecules.  
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As a whole, Canadian policies regarding the pharmaceutical industry are not seen as neutral by the generic pharmaceutical industry, since they appear to favour one sector of the at the expense of another. These obstacles have combined with a major reduction in potential market size for generic products in the past decade, due to the implementation of provincial drug plan changes and corresponding price reductions. The scope and speed of these changes has deeply affected the business models of generic firms, and will continue to do so given the scheduled reductions to be implemented over the next few years.

The generic industry was able to operate in this environment due to a series of factors specific to the Canadian market, and opportunities for timely market access and manufacturing flexibility as discussed above. However, such advantages do not compensate for the increasing disadvantages and uncertainties.

## 2.5 Concluding Remarks

A sizeable generic pharmaceutical industry has developed in Canada over the past five decades. Its intensive, ongoing R&D efforts have paid off in terms of increasing exports, which has allowed Canada to benefit from this high-growth market worldwide despite its limited size (2% to 3% of the world pharmaceutical market). Other countries have recently become competitors of Canada in attracting generic pharmaceutical investment because of natural advantages (e.g. size of domestic market, low costs) and beneficial policies and investment incentives. During the same period, Canada's investment climate became gradually less favourable to the development and viability of the generic pharmaceutical industry:

- Costs for manufacturing and R&D are at least 50% higher than in emerging countries. As such, its justification as an export base is being eroded;
- Canada's skilled labour is less of an advantage than in the past, as competing countries are closing the gap. High Canadian labour costs also serve as a deterrent to investment;
- Policies and regulations have presented increasing challenges.

Despite these factors, the generic pharmaceutical industry has continued to make investments in Canada<sup>26</sup>. Indeed, Canadian plants, despite higher production costs, have managed to control their cost disadvantage through manufacturing flexibility. In addition, the current rules have until now facilitated timely access to the Canadian and international markets for many pharmaceutical products, thereby insuring an ensuing competitive advantage compared to generic pharmaceutical firms which are absent from Canada.

While some challenges are caused by external forces, others could be alleviated by various policy adjustments in order to improve or at least stabilize the investment climate in Canada. However, the European Union's proposed changes to Canada's

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<sup>26</sup> Examples: Pharmascience announced a \$38 million investment project in the Montreal area in May 2011. Teva announced a \$56 million expansion in Stouffville, Ontario in July 2011.

legal and regulatory environment for pharmaceuticals in the CETA negotiations would not contribute to improvement or stabilization of the climate for Canadian generic pharmaceutical investment, as will be seen in the next section.

## 3. Potential Impacts of EU Proposals

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The generic industry has served as a watchdog for the brand practice of creating complex patent thickets.

The impact will be felt immediately by generic firms and more gradually by the Canadian economy.

In the long run, Canada could lose a financially healthy R&D-intensive industry.

• • •

The CETA negotiations between Canada and the EU include a chapter devoted to intellectual property (IP), and the European Union has proposed several changes to Canada's intellectual property regime for pharmaceuticals.

As noted in the Introduction, the EU Proposals call for a significant extension of the market exclusivity granted to brand-name pharmaceuticals in Canada even though it already offers one of the best protections in the world<sup>27</sup>. These Proposals are estimated to delay market entry of generic pharmaceuticals by an average of 3.5 years at a cost the Canadian health care system of almost \$3 billion annually<sup>28</sup>. As noted by Hollis and Grootendorst: *"If Canada agrees to the proposed EU IP provisions in CETA, Canada would provide the longest structural protection to patented pharmaceuticals in the world."*<sup>29</sup>

### 3.1 Impacts on the Generic Pharmaceutical Industry

The EU's proposed IP extensions will have various and compounded industrial effects on the generic pharmaceutical industry over time. These impacts are explored in detail below and are based on in-depth interviews with senior executives of the generic pharmaceutical industry, representing more than 90% of the industry's revenues in Canada.

#### 3.1.1 Short-to-Medium Term Impacts

The pharmaceutical IP extensions proposed by the European Union would delay and limit the potential of the generic pharmaceutical industry's Canadian and export markets.

- **Domestic market.** Timely market access currently drives the business model of generic pharmaceutical firms in Canada. A 'thicket' of secondary patents is typically developed by brand-name firms to prevent or delay competition from generic firms. Such patents, sometimes determined by the courts to be weak or frivolous, contribute to extending intellectual property protection for many years beyond the period allowed for the primary patent related to the original innovation. The generic industry has served as a watchdog for this brand practice of creating complex patent thickets, and has actively litigated weak and frivolous secondary patents to ensure Canada has access to cost-saving competition at the earliest appropriate opportunity.

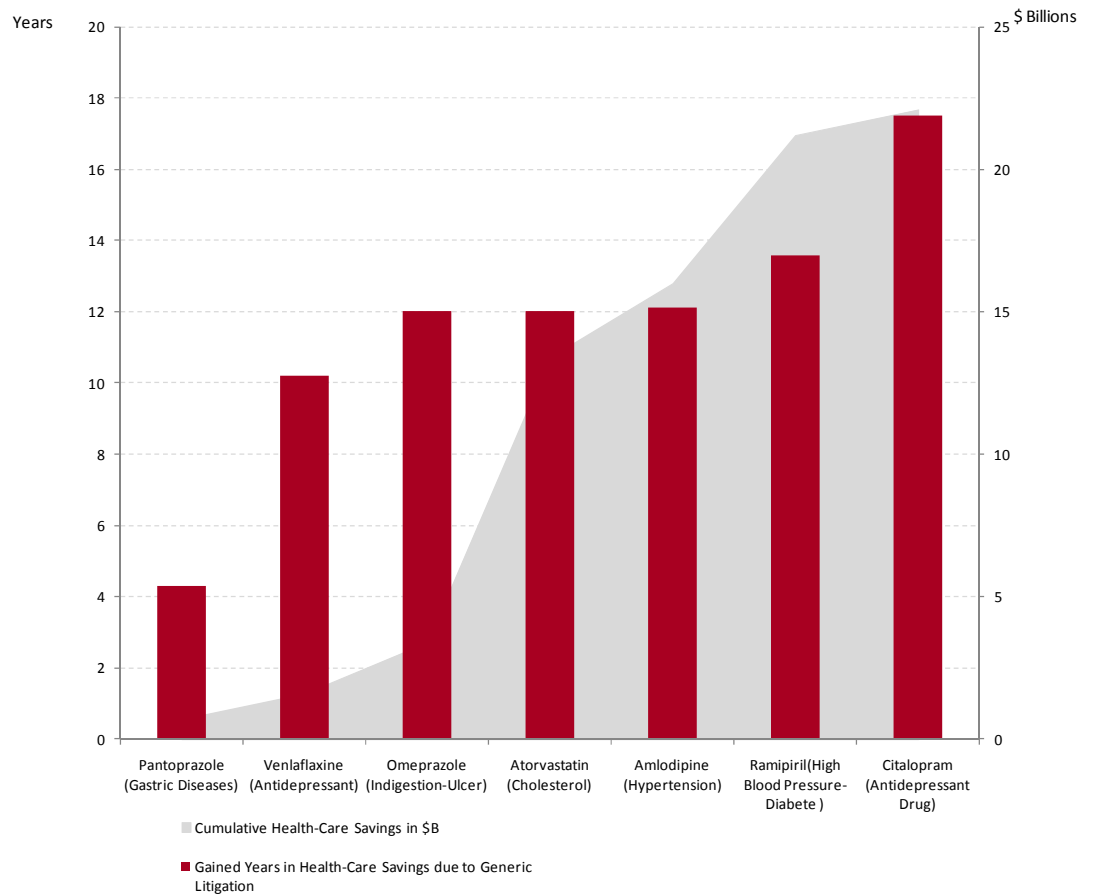
<sup>27</sup> Iacobucci. May 2011.

<sup>28</sup> Hollis and Grootendorst. February 2011.

<sup>29</sup> Hollis and Grootendorst, p. 6. February 2011.

Generic firms in Canada have been willing to challenge weak/frivolous patents and have been successful in doing so, winning approximately 70% of decided cases. Seven of the top 10 generic drugs currently sold in Canada are the result of litigation initiated by generic pharmaceutical firms, rather than the expiration of all patents associated with a brand-name product.

**Figure 2. Impact of Successful Generic Litigation of Weak/Frivolous Patents in Terms of Availability of Generic Drugs and Cost Savings – An Example From Seven of Canada’s Top Selling Generic Drugs**



Source: Analysis conducted for CGPA by the law firm Hazzard and Hore.

The current system permits a dual track of litigation on the same patent or set of patents, initiated by brand-name companies. This causes generic pharmaceutical firms, after success in a patent linkage case, to be subjected to a subsequent infringement action as available to patentees in all industrial sectors under Canada’s



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Corporate decision  
makers would  
inevitably allocate  
their resources in  
countries offering  
more attractive  
investment  
climates.  
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Patent Act. This dual track is a relatively new phenomenon in Canada, but has emerged as a common brand litigation tactic. A single loss for a generic firm under an infringement action could be catastrophic as the generic firm could be found liable for the brand firm's full monopoly profits. With lower margins as a result of recent reductions in retail generic prices, the generic firm's opportunities for extensive profit gains in a highly competitive multi-source environment are increasingly limited, and are many multiples below the monopoly profits earned by the brand-name firm.

Generic pharmaceutical firms already have a reduced incentive to challenge weak and frivolous patents because of a reduced potential market and increased risk exposure. By increasing the length and legal complexity of Canada's pharmaceutical IP regime as proposed by the European Union, generic firms will even have less incentive to seek market entry at the earliest opportunity. Consumers will be left to continue to pay high monopoly drug prices, even when the intellectual property protection granted to patent-holders is not warranted.

- **Export markets.** The significant delay in domestic competition associated with the EU CETA Proposals – an estimated average of 3.5 years – would also have a direct impact on the ability of Canadian generic firms to seek timely access to new export markets for generic drugs. Canada will therefore lose its rationale as an export base as opportunities in foreign markets are captured earlier by manufacturers operating within those markets or from jurisdictions without comparable barriers to trade.

In addition to the loss of future revenues, the implementation of the EU Proposals in Canada would create higher overhead and administrative costs. Further, the increased uncertainty related to legal outcomes would have the effect of increasing hurdle rates for development and litigation, reflecting the higher risk environment. As a result of higher costs, reduced market potential and increased hurdle rates, it is inevitable that less R&D will be conducted in Canada. The following outlines the impact the EU Proposals would have on the decision making process at the product level, as described by Canadian generic pharmaceutical executives.

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According to industry executives, level of activity of the industry could thus decrease by 20% to 30% on a short to medium term basis, when compared to current levels.  
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### Impact of CETA Proposals on a Generic Pharmaceutical Firm's Decision Making at the Product Level

*The impact of these aggregate location factors is to be considered when assessing the net present value (NPV) forecast for each new molecule. The NPV assessment for future molecules in Canada will thus be directly affected through:*

- *Reduced revenues and profitability, because of sliding prices and export limitations. Canadian producers will lose any timely market access opportunities they still had, thereby losing their share in export markets and in the domestic market due to increased competition from competitors who are developing and manufacturing products abroad.*
- *Increased costs, (mainly legal costs) as well as increased overhead, related to increased complexity. A patent linkage case is currently estimated to cost a generic company between \$1 million to \$3 million. The addition of an automatic 'right of appeal' would mean additional legal costs and forfeited expenses, or opportunity costs. In addition, generic firms are routinely subjected to subsequent infringement actions initiated by brand-name firms. The legal fees for these cases can be in excess of \$10 million.*
- *Increased hurdle rates, reflecting the increased complexity and volatility (lack of predictability) of future revenues (legal outcomes and liability risks).*

*A significantly reduced NPV will limit the number of molecules worth genericizing. Development will be limited to those molecules with superior market potential (return on investment).*

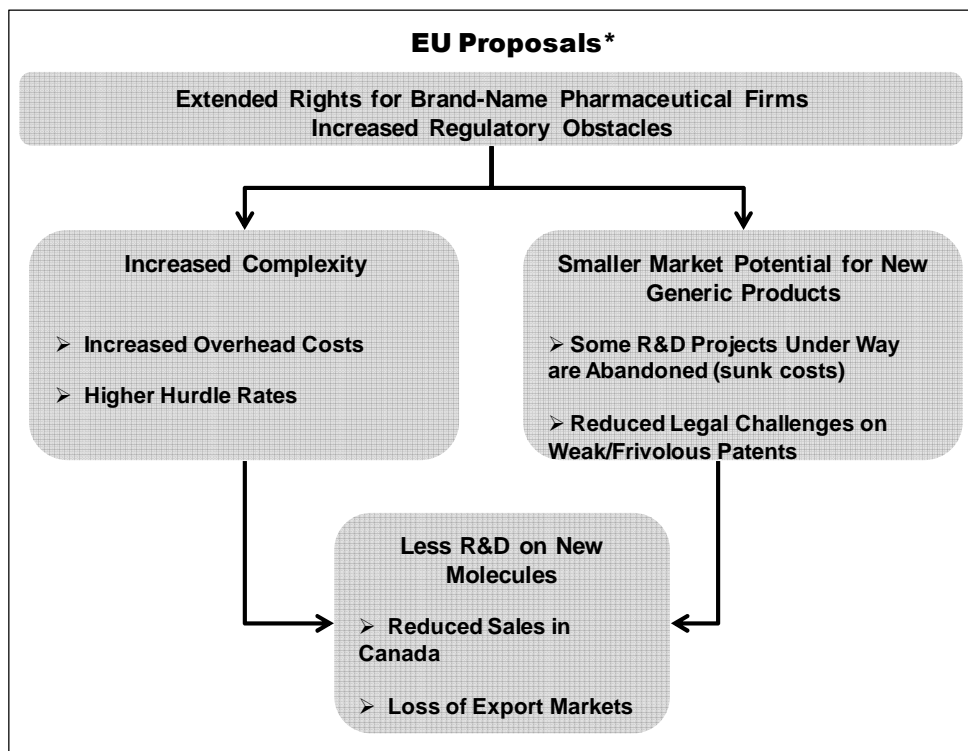
The loss of a timely market access, which was the key to Canadian generic pharmaceutical success in export markets, will mean that development for the Canadian market will no longer provide any strategic advantages for global generic pharmaceutical corporate headquarters. Indeed, as mentioned earlier in this document, Canada's market accounts for 2% to 3% of total corporate sales for most generic pharmaceutical companies active in the Canadian market. Whether they are located in Canada or abroad, corporate decision makers, faced with a marginal market whose profitability is being eroded, will inevitably allocate their resources in countries offering more attractive investment climates.

Although according to industry executives, the Canadian market could remain attractive for medium to large molecules (approximately \$50 million in brand sales

per year and higher), this is much less likely to be the case for smaller molecules. Accordingly, some pharmaceutical products may not be genericized, to the obvious detriment of the Canadian payers (including private and public drug plans) and patients. The level of activity of the industry could thus decrease an average of 20% to 30% on a short to medium term basis compared to current levels<sup>30</sup>.

The EU Proposals would also have a significant impact on the revenues of generic pharmaceutical firms in Canada. Some current R&D projects are unlikely to generate a minimum return on investment under the new business environment and will be abandoned. On a short to medium term basis, sunk costs for these molecules currently under development (generic drugs take an average of 3 to 6 years to develop) will not be recovered. The figure below summarizes the industrial dynamic process generated by the EU Proposals, should they be adopted.

**Figure 3. Industrial Dynamic Process Generated by EU Proposals**



\* Extended patent periods, extended data protection and additional appeal rights when originator loses a patent linkage case.

This situation will further worsen Canada’s investment climate for all three sets of location factors discussed in Section 2, as per the Figure on the next page.

<sup>30</sup> Estimate based on interviews with generic pharmaceutical industry executives representing more than 90% of the industry’s revenues in Canada. Some estimates were more pronounced, pointing to a 50% decrease in activity.

Figure 4. Impact of the IP Regime Extension

	CURRENT		PROPOSED	
	Trend	Detail	Trend	Detail
<b>Legal and Policy Environment</b>	↘	Dual litigation - increasing uncertainty, risk exposure and legal costs	↘	Increased complexity Increased length of legal proceedings Increased risk / less predictability
<b>Market Factors</b>	↘	Small market (2% to 3% of world market) Price reductions (drug plans)	↘	Delayed market entry and reduced market potential Smaller molecules not pursued
<b>Location Sensitive Cost Factors</b>	↘	Production labor R&D labor Clinical testing Overall corporate taxes (incl. tax incentives) Regulatory fees	↘	Sunk costs for molecules currently under development Increased legal costs Increased overhead

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*"Any activity that curbs the role of generic medicines could have disastrous consequences, not only for generics manufacturers but also, more especially, for patients as well as governments, payers and all other stakeholders involved in the delivery of healthcare."*<sup>31</sup>

### 3.1.2 Longer Term Impacts

Faced with a reduced domestic and export market potential in Canada, a sub-par investment climate and aging facilities while alternate locations abroad offer better conditions, the gap between the investment attractiveness of Canada and competing countries where those development funds are reallocated will therefore increase. This situation will raise the question as to whether future investments in Canada can be justified to maintain, let alone expand, generic pharmaceutical R&D and manufacturing capabilities in Canada.

Initially, global corporate headquarters will start by diverting production and R&D mandates to other company facilities abroad. The next step will be decisions to shut down facilities and consolidate activities outside of Canada. Jobs will be lost at the manufacturing and R&D levels, as well as within the domestic suppliers' network.

With the disappearance of industrial activities, only commercial activities (import and distribution) will be left. All major generic pharmaceutical firms in Canada are globalized or in the process of building such international networks and partnerships. In the long run, there is no reason why firms currently headquartered in Canada should favour staying in Canada if the investment climate is less competitive than elsewhere.

While the short and medium term impact described in the previous section is a 'game changer', the longer term impact will be a direct consequence of the reduction in R&D and the ensuing diversion of corporate financing to projects in other countries.

<sup>31</sup> IMS Health. *Generic Medicines: Essential Contributors to the Long-Term Health of Society*, March 2010.

## 3.2 Impacts on Canada's Economy

### 3.2.1 Short-to-Medium Term Impacts

On a short to medium term basis, Canada's economy will face gradual negative impacts in terms of industry investments, job creation/retention and exports. A delayed supply of new generics will mean higher overall prescription drug prices. In terms of outcome, similarities can be drawn with other countries, whose disincentives actually did have significant negative industrial effects.

Overall, the proposed changes would further decrease the attractiveness of Canada's investment climate for R&D, manufacturing and exports, and ultimately lead to facility shutdowns and international relocations. Canada will have lost the opportunity to benefit from the investment potential associated with a growing R&D-intensive industry worldwide. It will also have lost an opportunity to compensate for the structural difficulties of other sectors of the pharmaceutical industry in general in Canada.

### 3.2.2 Longer Term Impacts

In the long run, Canada runs the risk of losing its generic pharmaceutical industry to the detriment of Canadian payers, patients, workers and taxpayers.

In addition to job losses and a reduced contribution to international trade in pharmaceutical products, Canada will lose several aspects of its industrial activity:

- Manufacturing capacity and know-how. This loss of such a strategic asset could be felt vividly at a national level in the event of worldwide product shortages or pandemics.
- R&D infrastructure. This includes senior researchers, funding of university research centres and projects, including the emerging area of subsequent entry biologics.
- Investment. In addition to facility shutdowns, Canada will lose the opportunity to attract internationally mobile investment projects in the generic pharmaceutical industry.

From a macro-economic perspective, Canada will lose in terms of GDP impact, public finances (reduction in tax revenues, increased drug-related expenditures) as well as reduced exports and increased trade deficit. As discussed, should they be adopted, the EU Proposals would not only affect the cost of pharmaceuticals available on the Canadian market, but the entire industrial research and production chain for export.

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On a short to medium term basis, Canada's economy will face gradual negative impacts in terms of industry investments, job creation/retention and exports.

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### 3.3 Concluding Remarks

If enacted, the EU Proposals could be a breaking point for the industrial development of the generic industry in Canada. Although generic pharmaceutical companies are increasingly active internationally in both R&D and manufacturing investments, new and current projects in Canada would be at risk.

The shock to the domestic generic pharmaceutical industry would be immediate but its eventual departure from Canada would take longer to materialize, as the existing industrial infrastructure gradually becomes less productive than regularly upgraded facilities in competing countries.

## Conclusion

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EU Proposals could cause Canada's public sector to lose on several respects:  
1) prescription drug expenditures,  
2) external trade,  
3) industrial benefits.

It is to be expected that the impacts on GDP and on public finances would be significant.

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The generic industry in Canada currently has almost the same size (e.g. employment levels) as the brand-name pharmaceutical industry. Because the generic industry contributes a great deal to Canadian society and public finances while receiving minimal financial support, it is not unlikely that its net contribution to the Canadian economy and public finances exceeds that of the brand-name pharmaceutical industry. This contribution is now at risk.

Should Canada lose its timely domestic and international market access advantage as a result of the EU Proposals in the CETA negotiations, fewer generic molecules will be developed in Canada. According to generic pharmaceutical industry executives, the level of activity of the industry is expected to decrease by 20% to 30% compared to current levels on a short to medium term basis and its long term presence will become highly questionable.

The consequences would be felt on employment, exports and investments. Public finances would also be directly affected. Without challenges by generic pharmaceutical companies to the weak and frivolous patents of brand-name firms, drug prices will remain high in comparison to other countries. Expected savings from generic pharmaceutical sales will not materialize, compounding the loss of the positive tax contribution resulting from current generic pharmaceutical industry operations in Canada. Eventually, the availability of generic pharmaceutical products in Canada could decline.

The industry will have lost its capacity to contribute to Canada's economy and public finances. Ultimately, the private and public sector payers, consumers and taxpayers would pay the price.