*Canada's Research-Based Pharmaceutical Companies* **(Rx&D)**

# Pre-Budget Submission
# House of Commons Standing Committee on Finance

**August 12, 2011**

# Executive Summary

On behalf of *Canada's Research-Based Pharmaceutical Companies* (Rx&D), 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 advance Canada's competitiveness and prosperity.

Rx&D is the national association representing more than 15,000 men and women who work for 50 research-based pharmaceutical companies in Canada. Rx&D companies are committed to Canada and invest in private sector health science and technology-based R&D throughout Canada. In 2010, Rx&D members invested $1.5 billion in Canada, including approximately $1.3 billion in scientific research and development. An additional $90 million was provided in product donations to patients through compassionate care and special programs, and $120 million in contributions were made to such community-based programs as breakfast for learning in schools, sports and recreation, environmental responsibility and land and wildlife preservation.[1] Our network of partnerships and collaboration represents tens of thousands jobs and an investment of more than $20 billion over the last two decades.

In the current environment, however, this capacity to invest is under increasing pressure. The Canadian industry is evolving to reflect domestic market conditions and our competitiveness versus other global jurisdictions. Competitor nations have also recognized and implemented policies to capture the significant economic value-creation and health benefits inherent in a strong research-based pharmaceutical industry. Although our shared achievements of the past create a uniquely Canadian platform for future success, we must act urgently together in order to restore Canada's Life Sciences leadership and sustain an attractive investment climate.

Accordingly, we recommend three specific areas for policy action leading into Budget 2012. These steps will improve Canada's health care sustainability and future economic growth:

1. Improvements to **Canada's intellectual property (IP) regime**, including an effective right of appeal for innovators in the *Patented Medicines (Notice of Compliance) Regulations* in order to address an existing legal imbalance; improve our existing **Data Protection (DP) Regulations** to more internationally competitive levels**;** and implement a **Patent Term Restoration** regime similar to that of our major trading partners and competitors;

2. Securing Canadian leadership in **Clinical Research**, through a more expansive definition of Scientific Research and Experimental Development (SR&ED) tax credit and a reallocation of existing budgets to augment current research and infrastructure programs; and

3. Improvements to the **efficiency of Health Canada's regulatory review processes for drugs and biologics**, including ensuring the financial integrity of the Department's activities through an equitable and effective cost-recovery process that does not negatively impact core operations budgets.

It is important to note at the outset that many of these measures can be introduced at no or very limited cost to the federal government with significant economic return. These steps must be taken to protect the crucial health, life sciences and technology research infrastructure that Canada has built over many decades. In order to answer the challenge posed by an ever-expanding set of global alternatives, Canada must move quickly to streamline its Life Sciences policy environment to keep pace.

[1] KPMG, Summary of Pharmaceutical Survey Findings on R&D Spending and Investments by Rx&D Members - 2010

# 1. A Stable and Competitive Intellectual Property (IP) Regime

A competitive intellectual property regime is integral to our industry's ability to partner with the government on public health and prevention initiatives. Unfortunately, Canada's IP regime is uncompetitive with comparator nations and must be brought up to international standards if Canada is to fully benefit from our investments health research capacity.[2] For example, in several cases, innovator patents that have been upheld as valid in United States, European nations and in other jurisdictions have been invalidated in Canada as a result of adverse court decisions. Such anomalous judicial outcomes have damaged Canada's reputation and are an unfortunate disincentive for international innovative life sciences investments.

To stabilize and improve the IP environment, the Government of Canada should create an effective appeal mechanism for innovators under the *Patented Medicines (Notice of Compliance Regulations* ("NOC Regulations'); improve our existing Data Protection (DP) Regulations to more internationally competitive levels; and implement a Patent Term Restoration regime similar to that of our major trading partners and competitors.

As our industry is global in reach and scope, we look forward to the successful completion of the ongoing negotiations towards the Comprehensive Economic and Trade Agreement (CETA), which represents an important opportunity to address the IP issues set out below.

**An Effective Appeal Mechanism under the Patented Medicines (Notice of Compliance) Regulations.**

The Patented Medicines (Notice of Compliance) Regulations (NOC Regulations) provide a system that encourages patent infringement issues to be resolved before a generic drug enters the market. To benefit from this system, an innovator must list its patents on a patent register. While generics always have an appeal under the NOC Regulations, innovators often do not have an effective appeal right. The result is inequitable and has resulted in one-sided jurisprudence. It should be noted that there is growing Provincial and stakeholder momentum in support of the Federal Government making such a change. A regulatory amendment to create a time-limited but effective innovator appeal mechanism is urgently needed to restore balance in the operation of the NOC Regulations.

**Improve the Data Protection Regulations**

To get their medicines and vaccines approved, innovators invest substantial time and effort in clinical trials and tests to demonstrate the safety of their products and must submit this data to Health Canada. Canada's Data Protection Regulations protect this clinical and other test data from being used by generic competitors for a time-limited period. This prevents generic drug makers from unfairly utilizing the work of innovators in seeking approval of their generic copies of innovative drugs. Data Protection does not extend innovator patent protection, but rather protects the clinical trial data developed by innovators to ensure that that their products are safe for Canadian patients.

Canada's current DP regime remains deficient compared to some of its key competitors. For example, the European Union (EU) provides innovators with 2 years more data protection than Canada, and unlike Canada, also provides an additional 1 year of data protection for approved new uses of existing medications. Furthermore, under its recent healthcare reform legislation, the United States now provides 4 more years of Data Protection for innovative biologics than Canada, which is of particular importance to the future of the innovative industry given that biologics are projected to replace traditional small molecule medicines in the near future .

[2] Canadian Chamber of Commerce, *Innovation for a Better Tomorrow – Closing Canada's Intellectual Property Gap in the Pharmaceutical Sector* (2011).

Canada should increase the term of Data Protection offered to innovators to that provided by its major trading partners, and should extend Data Protection to cover approved new uses of existing medications. Given that the EU provides two more years than Canada for any product, and the U.S. provides four more years for biological products, Canada's competitive disadvantage is clear.

**Implement Patent Term Restoration.**

Like all developed nations, Canada provides innovators with a 20-year term of protection. However, 8 to 10 years of the patent term is eroded due to the time required to develop products based on the patents. In addition, the effective patent term for new medicines and vaccines in Canada is shortened due to the length of time it takes for clinical testing, drug reviews and approvals (including processes required by Health Canada, provincial/territorial governments, and the Common Drug Review). As a result, the current effective patent life of a pharmaceutical product in Canada is reduced by 2.5 to 3.5 years due to various government approval regimes.

In recognition of the significant government-imposed delays attributable to approval processes, more than 30 other countries have adopted a mechanism called patent term restoration (PTR). PTR helps innovators recoup more of their investment costs by restoring part of the patent term eroded by regulatory delays. Unlike the United States, Japan, Australia, South Korea and the 27 Member States of the European Union, Canada does <u>not</u> have any form of PTR, placing us at a distinct disadvantage to key competitors for jobs and investments.

## 2. SR&ED and Leadership in Clinical Research

Clinical research builds knowledge about the Canadian population and its health, develops the research capacity and global connections of Canadian researchers, and is a key link in the commercialization of research. Taking steps to improve clinical research in Canada is a means of improving both the health of Canadians and the health of our Life Sciences sector. Unfortunately, Canada's share of global clinical research activity, once one of the most active per capita in the world, is being eroded by other areas where research quality is on par with Canada and the costs are lower.

Almost 80% of the research funds our members invest in Canada are in clinical research and clinical trials. The principal policy tool available to incentivize private sector R&D is Canada's Scientific Research & Experimental Development (SR&ED) tax credit. Future success in attracting research investments in clinical trials and other key areas depends on an enhanced SR&ED system. **As we recommended in our submission to the Expert Panel on R&D earlier this year, required improvements to SR&ED include expanding the definition of eligible research to better capture all aspects of clinical research, including all direct investments in clinical trials, as well as complementary investments in other forms of research partnerships not currently eligible for SR&ED credits.**

At the same time, Rx&D estimates that approximately 20% of currently allocated clinical research funding, representing tens of millions of dollars, remains untapped. This lack of utilization is largely due to a lower level of awareness of trial opportunities, a patchwork clinical trial infrastructure, and an overall lack of capacity to implement trials. Countries like the United Kingdom (UK) and Spain have in recent years implemented an enhanced policy framework which includes the creation of support network for specific therapeutic areas, reimbursement of candidate drugs to patients once the trial is finished, monitoring and support systems to benchmark efficiency in clinical trial implementation.

Given this situation, timely adjustments to Canada's current clinical research capacity must be made if we are going to capitalize on current levels of private funding, let alone attract future investments. In particular, existing funding and programs through the Canadian Institutes of Health Research (CIHR) and the Canada Foundation for Innovation (CFI) must be assessed holistically within a framework approach to better facilitate clinical trials in Canada.

**To ensure that Canada retains and grows its clinical research capacity, the federal government should lead by expanding the definition of SR&ED-eligible research to ensure all aspects of clinical research and clinical trials are captured; reallocating CIHR funding to address gaps in clinical research; and reallocating funds to the Canada Foundation for Innovation (CFI) to provide needed infrastructure support.**

## 3. More Efficient Health Canada Reviews of Drugs and Biologics

Canadian patients are waiting longer than necessary for innovative medicines due to persistent delays in the regulatory process. Comparing average median of delays, a submission to Health Canada takes 390 days, more than the 350 days in the United States and almost 100 days longer than Europe's 275 days.[3] These delays are due largely to demand outstripping the resources available as well as other aspects of the review process employed, despite past government attempts to improve performance primarily through cost recovery as embodied in the *User Fee Act*.

**As we noted in our submission to the Red Tape Reduction Commission this spring, the federal government must ensure that Canadians have timely access to safe and effective innovative medicines by structuring Health Canada's core funding to support an expanded and more efficient and equitable review capacity, including but not limited to the consideration of international reviews and best practices. Further, any fees collected under cost recovery must be explicitly linked to performance targets and must not be offset by any reduction in the Department's core funding.**

Rx&D members are working diligently with officials on regulatory changes to modernize the drug approval regime in Canada. Maintaining momentum on this modernization exercise is imperative for our industry.

## Conclusion

Our country has a strong research base to build upon and many key ingredients for success in an increasingly competitive global research environment. This base includes multi-year investments by Governments in the public research enterprise, private investments by our members measuring $1.5 billion last year in direct R&D, and globally recognized clinical research capacity.

We must continually strive to maintain our competitive edge if we are to benefit from the potential within our innovative, knowledge-based industries. Rx&D is prepared to play its part. Going forward, our challenge is to work together on improving the policy environment by:

1. Implementing a globally competitive **intellectual property (IP) regime,** in particular by implementing an effective right of appeal for innovators within Canada's Patented Medicines (Notice of Compliance) Regulations; improve our existing Data Protection regime; and implement a Patent Term Restoration regime similar to that of our major trading partners and competitors;

2. Securing Canadian leadership in **Clinical Research**, particularly by enhancing the SR&ED credit; and

3. Improving **Health Canada's regulatory review processes.**

Rx&D appreciates the opportunity to advance these important policy proposals with the Standing Committee on Finance, and we look forward to having the opportunity to elaborate on our submission before the Committee this fall.

[3] Source: Health Canada Regulatory Approvals Performance Summary (2010)