

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

Responses

1. Economic Recovery and Growth

Given the current climate of federal and global fiscal restraint, what specific federal measures do you feel are needed for a sustained economic recovery and enhanced economic growth in Canada?

Rx&D commends the Government of Canada for its unwavering focus on its Economic Action Plan, first articulated in Budget 2009. In addition, complementary efforts including the Advantage Canada Economic framework, the Regulatory Cooperation Council and the recent upgrade to the Global Commerce Strategy are also supported by our members. Specific federal measures that will allow Canada's innovative pharmaceutical industry to contribute to a sustained economic recovery include:

- Concluding the Comprehensive Economic and Trade Agreement (CETA) with the European Union including the harmonization of Canadian intellectual property (IP) protections for life sciences – an effective right of appeal, patent-term restoration and increased data protection – to internationally competitive levels;
- Continued federal leadership and investments – as seen in Budget 2012 – in Canada's research infrastructure;
- Working in partnership with Rx&D, the Canadian Institutes of Health Research (CIHR) and the Association of Canadian Academic Healthcare Organizations (ACAHO) to resource and implement a national Clinical Trials Action Plan to re-establish Canadian leadership in this crucial field of knowledge translation and commercialization;
- Revisiting Budget 2012 proposed changes – through the regulatory process – to the Scientific Research & Experimental Development (SR&ED) to better reflect and reward the external and encompassing nature of clinical research across the life sciences ecosystem and to improve Canada's ability to attract R&D mandates from multinational companies; and
- Improving the efficiency of Health Canada's regulatory review processes for drugs and biologics and improving the vaccine evaluation and recommendation process.

Twenty-five years ago, the Government of Canada made a strategic decision to bring Canada into the mainstream in life sciences IP – and the results have been staggeringly successful. Investments by Rx&D members grew by 1,500% from \$93 million in 1987 to \$1.3 billion in 2010 creating jobs for Canadians and driving better health outcomes. Our proposed measures will result in more inward pharmaceutical investment into Canada resulting in high-skill, high-value employment opportunities and growth which will provide Canadian governments (federal, provincial and territorial) an enduring return on the substantive public infrastructure investments made into our colleges and universities, research institutes, academic health science centres and bodies such as CIHR and Genome Canada.

2. Job Creation

As Canadian companies face pressures resulting from such factors as uncertainty about the U.S. economic recovery, a sovereign debt crisis in Europe, and competition from a number of developed and developing countries, what specific federal actions do you believe should be taken to promote job creation in Canada, including that which occurs as a result of enhanced internal and international trade?

Rx&D members account for high-quality jobs. Our indirect and induced economic footprint through research partnerships, alliances, and other professional value-chain services and activities – the Canadian life sciences "ecosystem" – accounts for advanced, knowledge-based jobs that allow Canada to benefit from expertise in the sciences, medicine and business. As noted strategy economist Michael

Porter has observed, economic competitiveness needs to be the cornerstone of macroeconomic policy from which sustained job creation will result. Indeed, one of our foundational concerns is that Canada maintains and improves its economic framework through the measures articulated in our answer to the committee's Economic Recovery and Growth question which will improve the investment climate that supports important life sciences sector jobs. Rx&D member companies have invested over \$20 billion in scientific research and development – in fact we are the largest funders of health and health outcomes research in Canada – over the past two decades. Moreover, our sector invests more than \$110 billion globally on an annual basis and is the most R&D intensive sector (a critical element for post-industrial economies like Canada) amongst all industries worldwide. However, through more competitive IP regimes and more streamlined regulatory environments (which do not compromise patient safety), other nations – both developed and developing – have surged ahead of Canada as favourable destination for our R&D investments. Today, Canada represents 2.34% of world pharmaceutical sales but attracts just over 1% of total R&D investments on an annual basis. If Canada is to address this gap and spur high-value, high-skill job creation, a concerted effort must be made by the federal government (and its provincial/territorial partners) to implement the measures proposed in response Question 1 to attract more investments from our sector, especially in the realm of clinical trials, which will positively impact each jurisdiction in the federation and more importantly, improve health outcomes for Canadians resulting in a stronger and more resilient labour force. The implementation of these measures would send an important signal to the international life sciences industry that Canada is determined to create a positive environment for future investments.

3. Demographic Change

What specific federal measures do you think should be implemented to help the country address the consequences of, and challenges associated with, the aging of the Canadian population and of skills shortages?

The relationship between demographics, specifically an aging population, and healthcare demand is well documented. Moreover, Canadians – and their governments – are rightly concerned about the sustainability of our healthcare system. Innovative medicines and vaccines help prevent and manage the chronic diseases which impact a growing number of Canadians, including the elderly. These treatments are contributing to better outcomes in many areas including diabetes, cancer, cardiovascular disease, arthritis, and mental health. In addition, medicines and vaccines are now used to treat conditions for which no treatments were available just a generation ago and the future for Canadian patients is bright given the development and scientific advancement in our members “pipelines” including:

- 900 potential medicines to treat cancer;
- 395 candidates to combat infectious diseases;
- 300 promising therapies in the field of mental health;
- 200 new therapeutic approaches to pain management; and
- 100 novel Alzheimer's therapies in development.

The appropriate use of medicines – the right medicine to the right patient at the right time – has been documented to improve health outcomes. According to the OECD, over the last 30 years, pharmaceutical interventions have helped to:

- Reduce the death rate from heart disease by 74%;
- Reduce the death rate from HIV/AIDS by 78%; and
- Reduce the death rate from Bronchitis, Asthma and Emphysema by 88%.

During this same period, OECD data also indicate that proper use of medicines and vaccines has contributed to dramatically reduce hospitalization rates by:

- 50% for asthma patients;
- 72% for breast cancer patients; and
- 70% for prostate cancer patients.

Ensuring that all Canadians can benefit from new medicines will require the federal government to ensure an up-to-date policy environment that supports the innovative potential of the life sciences sector to invest and prosper. This includes a globally competitive IP regime that attracts clinical research into diseases and conditions that impact seniors and all Canadians. The appropriate use of medicines and vaccines reduce the incidence of more costly system interventions such as physician visits, hospital admittance and invasive surgeries. Providing more timely and

comprehensive access to these medicines is sound public policy.

4. Productivity

With labour market challenges arising in part as a result of the aging of Canada's population and an ongoing focus on the actions needed for competitiveness, what specific federal initiatives are needed in order to increase productivity in Canada?

Productivity, for post-industrial economies such as Canada's, can be defined as the production of high-value goods and services per unit of human, capital and natural resources deployed. The Conference Board of Canada ranks this country a disappointing 14th in the world in terms of national productivity and on the decline. The OECD has noted our persistent productivity gap as our productivity has actually fallen since 2002 while U.S. productivity has grown by around 30% over the last 20 years. Our different approaches to the adoption of innovative technologies, including pharmaceuticals and vaccines, are an important clue to understand this difference. Innovation is the enabler of improved competitiveness and productivity. Innovation benefits employers and employees, producers and consumers, and governments and citizens. Canada has lost its competitive edge in attracting life sciences investment. Our key life sciences competitors have recognized the need for policies to capture the significant health benefits and value-creation that come with a strong pharmaceutical industry and have moved to strengthen their intellectual property regimes. As Canada proceeds to conclude the CETA trade negotiations with the EU, we strongly urge the inclusion of three essential changes to restore Canada's life sciences leadership, while supporting health care sustainability and improved innovation and productivity:

- Create an effective appeal mechanism under the Patented Medicines (Notice of Compliance) Regulations to level the playing field between innovators and generics; it's a simple matter of fairness;
- Improve the term of data protection offered (from 8 to 10 years) to innovators to and extend data protection to cover approved new indications for existing medicines; and
- Implement patent term restoration (PTR) to compensate for government and other delays in regulatory and approval processes by partially restoring the patent term eroded by these delays. Canada is just one of three out of 34 OECD nations that do not provide any form of PTR. The stability, predictability and the competitiveness of Canada's IP regime—one that stimulates and rewards innovation—is critical to the future success of this country's productivity, as well as to the ability of our sector to attract Canada's share of global pharmaceutical investment.

5. Other Challenges

With some Canadian individuals, businesses and communities facing particular challenges at this time, in your view, who is facing the most challenges, what are the challenges that are being faced and what specific federal actions are needed to address these challenges?