

Standing Committee on Finance (FINA)

Pre-budget consultations 2012

Johnson Johnson Family of Companies in Canada

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?

To ensure ongoing economic recovery and create the conditions to enhance competitiveness and growth in the health care products sector, regulatory modernization of the Food and Drugs Act is required to enable Health Canada to regulate therapeutic products throughout their life cycle. The Federal Government made a positive step in this direction in Budget 2012 by removing the requirement for regulatory amendments to declare prescription status for new drugs, or to switch their status from prescription to non-prescription status under the Food and Drugs Act. J&J strongly supports this move and encourages the Federal Government to implement it expeditiously to increase access to products which enable Canadians manage their own health care and ensure better patient outcomes per dollar spent. The Johnson & Johnson Family of Companies in Canada (J&J) encourage the federal government to commit to the following actions in Budget 2013 to enhance growth in our sector:

- Implement regulatory modernization of the Food and Drugs Act, including:
 - o Introduce regulations for drugs for rare diseases (also called orphan drugs). J&J recommends that Canada's regulatory approach to orphan drugs aligns with regulations in place in the United States and European Union, including specific intellectual property protections (namely data exclusivity) to support research and investment in drugs to treat rare diseases.
 - o Develop a separate regulatory framework for over-the-counter products.
 - o Ensure that any proposed labeling changes are aligned with the requirements of other global jurisdictions.
- Ensure that Canada's policy on subsequent entry biologic products is science-based and has a focus on patient safety.
- Introduce a regulatory framework for the reprocessing or refurbishing of single-use medical devices in the regulatory modernization initiative.
- Support the efforts of the Canada-United States Regulatory Cooperation Council to implement the Joint Action Plan Initiatives for health and personal care products on schedule. These measures would make Canada more competitive in the global biopharmaceutical industry, which invests in excess of \$110 billion per year. Enabling Canada to be more competitive will help increase our share of the significant R&D funds invested in the industry globally and contribute to Canada's high-skill, high-value workforce and economy.

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?

To promote job creation, Canada needs to ensure that its business environment is globally competitive. The Canada-European Union Comprehensive Economic and Trade Agreement (CETA) currently being negotiated is a key opportunity to achieve this objective. Intellectual property protection for pharmaceuticals is a key component of those negotiations. A competitive intellectual property regime will enable Canada's domestic innovative pharmaceutical industry can continue to compete with its global counterparts. J&J supports Canada agreeing to the three key pharmaceutical intellectual property reforms under discussion in CETA negotiations, including:

- An effective right of appeal for innovators in

patent challenges; •Ensuring that data protection for pharmaceuticals meets or exceeds that offered by the EU; and •Implementing patent term restoration to offset regulatory approval and other delays to market new, innovative medicines. A successful conclusion to the Canada-EU CETA that enhances Canadian IP protections will also place Canada in a very positive position for future trade negotiations, such as bilateral discussions with India and Japan, as well as upcoming negotiations with the members of the Trans-Pacific Partnership. In addition to trade agreements, the Regulatory Cooperation Council with the United States is also a key opportunity to reduce unnecessary and cumbersome regulatory differences between Canada and the United States. J&J supports the announced initiatives of the RCC in the 2011 Joint Action Plan and encourages ongoing effort towards reducing regulatory barriers with Canada's main trading partner.

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 aging Canadian population will place increased pressure on the entire spectrum of the health care system, including the use of pharmaceuticals and medical devices, support for chronic disease management and self-care products to support prevention and care. J&J is committed to supporting Canadians, their health care and the health care system by bringing innovative ideas, products and services to Canada to advance the health and well-being of Canadians while ensuring better patient outcomes per dollar spent on healthcare. Budget 2012 committed to reduce red tape by removing the regulatory requirement switch products from prescription to over-the-counter status. This is a positive development which will empower Canadians to better manage their own health care and reduce burdens on the health care system. J&J recommends that the Federal Government extend their support of self-care options for Canadians through targeted tax incentives, such as the removal of GST on over-the-counter products or tax deductibility of over-the-counter products. J&J is also committed to working with its partners in the pharmaceutical and self-care industries to address the issues of drug shortages. We encourage ongoing support for the activities of the Drug Shortages Working Group as they work towards establishing a solution for Canada. Further, implementing regulatory modernization of the Food and Drugs Act will also ensure that all Canadians, regardless of age, have more timely access to safe, effective, innovative new medicines, easing the burden of disease and ensuring that the right treatment is available to Canadian patients when they need it.

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?

To increase productivity in Canada, the business environment for J&J and the broader health care products sector, the Federal Government can undertake specific initiatives, including: •Regulatory modernization of the Food and Drugs Act; •Ensure regulatory alignment and cooperation with major trading partners, including the US via the Regulatory Cooperation Council and implementation of its 2011 Joint Action Plan; •Continuing to enhance Canada's trade relationships with key jurisdictions, particularly the European Union and the Trans-Pacific Partnership; and •Strengthening Canada's intellectual property regime for pharmaceuticals by implementing an effective right of appeal for innovators in patent challenges, extending data protection for pharmaceuticals and implementing a patent term restoration to offset regulatory approval and other delays to market. These steps will increase Canada's competitiveness for investment. As part of a global business, the J&J Family of Companies competes not only with our competitors within the same sector domestically, but also with

our own J&J counterparts around the world. Ensuring that Canada's business environment remains competitive will help create the conditions needed for our Canadian operations to compete for and win investments on the global stage.

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?

Health care is an industry worth investing in. Thousands of Canadians are employed in the sector, fulfilling high-skill, high-value roles in the medical, clinical, technical and scientific fields. Even more Canadians rely on the health care system every day as patients. As health care evolves towards preventive care, management of chronic diseases and addressing the needs of an aging population, Canada can lead by investing in this sector and helping to ensure better patient outcomes for every dollar spent on health care. Budget constraints are a reality across the board in Canada at all levels of government. J&J encourages governments to focus on ensuring that efforts to innovate and reform the health care system result in better patient outcomes per dollar spent. A key component of achieving that result is making timely access to innovative new treatments to treat disease and manage chronic conditions a priority for the system. While health care delivery is a provincial responsibility, the Federal Government can support the goal of better patient outcomes by supporting innovation in health care taking the following actions:

- Supporting a competitive business environment in Canada via regulatory modernization of the Food and Drugs Act;
- Ensuring that Canada's intellectual property regime is enhanced and competitive with other leading jurisdictions, such as the European Union and the Trans-Pacific Partnership; and
- Investing in health care innovations, in partnership with industry, to ensure that the best and brightest Canadian ideas are commercialized at home and benefit Canadian patients.