Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

Executive Summary

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J), we are pleased to submit the following priorities as the Committee develops its recommendations to the Government for the 2015 Federal Budget.

The Johnson & Johnson Family of Companies in Canada (J&J) provide recommendations to the Standing Committee on Finance, focusing on two of the six key themes identified by Committee, namely:

- Increasing the competitiveness of Canadian businesses through research, development, innovation and commercialization; and
- Improving Canada's taxation and regulatory regimes.

Under the first theme, **increasing competitiveness**, J&J's priority recommendations include:

- Timely implementation of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA). Measures included in the agreement, including intellectual property protection for pharmaceuticals, will increase Canada's competitiveness, support innovation and increase investment in clinical research and development.
- Building on the launch of the Canadian Clinical Trials Coordinating Centre by further increasing its efficiency and competitiveness, in order to enable the program to help attract even greater investment in clinical trials in Canada.

Under the second theme, our priorities focus on **improving Canada's regulatory regimes** by:

- Supporting the completion of ongoing initiatives while advancing the next phase of work of the Canada – United States Regulatory Cooperation Council (RCC).
- Ensuring that regulatory modernization initiatives undertaken at Health Canada to enhance and improve the *Food and Drugs Act* are supported with adequate financial and human resources and continued public engagement and consultation.

In addition, J&J urges the federal government to consider greater flexibility in how its financial contribution is applied and utilized by the Canadian Agency for Drugs and Technologies in Health (CADTH), particularly as related to performance measures of the Common Drug Review's drug submission processes.

Implementing these measures as part of the 2015 Federal Budget will increase the competitiveness of Canada's innovative biopharmaceutical and health products industries, directly contributing to economic growth and increasing the opportunity for further life science investments in the Canadian marketplace.

Pre-Budget Submission

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J) and our 2,500 employees across Canada, we appreciate the opportunity to offer our policy priorities for the 2015 Federal Budget, representing the single, unified voice of our Canadian operating companies and divisions.

Increasing Competitiveness

***Priority**: Canada-European Union CETA Implementation*

J&J strongly supports strengthening the Canadian economy via enhanced free trade. The Canada-EU Comprehensive Economic and Trade Agreement (CETA) offers the innovative life sciences sector an historical opportunity to make Canada a more competitive environment for research and development, which will create jobs and support increased economic activity. CETA will support the development of new medicines and vaccines both to improve health outcomes and contribute to the Canadian health system's overall sustainability.

Intellectual property protection is a key success factor for the life sciences sector. J&J believes that the stability, predictability and global competitiveness of Canada's IP regime—one that stimulates and appropriately rewards innovation—is critical to the future success of this country's research productivity.

We strongly urge Canada to implement CETA in an expeditious manner in order to begin to realize its evident benefits for Canada and the Canadian economy as quickly as possible.

***Priority**: Enhance the Canadian Clinical Trials Coordinating Centre*

Canada has to be nimble and competitive to attract investment in life sciences research and development for therapeutic products. Support for clinical trials, through the Canadian Clinical Trials Coordinating Centre (CCTCC), is highly complementary to efforts to improve intellectual property protection.

Announced in April 2014, the CCTCC is a collaborative effort of the Canadian Institutes of Health Research (CIHR), Canada's Research-Based Pharmaceutical Companies (Rx&D), and the merged organizations of the Association of Canadian Academic Healthcare Organizations and the Canadian Healthcare Association (ACAHO/CHA).

The CCTCC is working to address a number of deficiencies in Canada's global competitiveness for attracting clinical trial investments, in particular the lack of a common contract to facilitate research between researchers and industry and the lack of harmonized research ethics processes that permit timely and expedited reviews of multi-centre trials.

Ensuring that the CCTCC is adequately resourced to continue its important work addressing these gaps in the Canadian environment will be instrumental to improving the Canadian clinical trial investment landscape and create opportunities for greater clinical trial research and investment in Canada from companies like J&J.

J&J recommends that the federal government, through the existing CIHR Strategy for Patient-Oriented Research (SPOR), provide stable, predictable, long-term funding to the CCTCC

beyond its initial three year mandate while seeking further opportunities to leverage other resources, including at the Provincial level.

Improving Canada's Regulatory Regimes

> ***Priority****: Support Next Phase of the Canada-United States Regulatory Cooperation Council*

J&J has been a leading supporter of the Canada-United States Regulatory Cooperation Council (RCC) from its inception. We view the RCC as a potentially powerful vehicle to strengthen regulatory efficiency in both Canada and the United States.

J&J has served as an active contributor to the various stakeholder sessions, and we fully intend to continue this constructive engagement with officials on both sides of the border going forward. J&J encourages the RCC leadership to maintain stakeholder engagement as a necessary component of its activity, irrespective of the specific issue under consideration. Ultimately, it will be the private sector which will need to work to achieve compliance in each jurisdiction, and the practical perspective of implementation must be reflected in any regulation and its related guidance and policies.

Completion of the first phase of the RCC's work, particularly that of its Health and Personal Care Products Working Group, will reduce administrative burden on both sides of the border without compromising safety. Important progress has been made to establish a Common Electronic Submission Gateway, which will deliver operational efficiencies while maintaining (and strengthening) appropriate scientific oversight of therapeutic and consumer products. Further work is required to advance other important first phase activities, such as aligning Good Manufacturing Practices inspections, enforcement and compliance. J&J urges the federal government to support and resource these efforts in Budget 2015.

In addition, the work of the RCC should now be looking forward to the future. J&J would recommend that the following policy areas would benefit from the unique structure of the RCC given their relevance to both the private sector and regulators in both jurisdictions:

- Biosimilars (Subsequent Entry Biologics)
- Orphan Drugs
- Post-Marketing Surveillance
- Product Classifications/Definitions
- Over-the-Counter Product Monographs
- Electronic Labelling, especially for medical devices

Budget 2015 should empower the RCC to identify future areas of focus in order to reduce the burden of regulatory compliance and increase competitiveness on both sides of the border.

> ***Priority****: Regulatory Modernization of the* Food and Drugs Act

J&J has consistently been a leading voice in support of modernizing Canada's legislative and regulatory tools for therapeutic products, especially in regard to the longstanding need to update the *Food and Drugs Act*. It is important that the federal government has all relevant powers at its disposal to ensure the appropriate evaluation, introduction, and post-market management of therapeutic products, including prescription drugs, medical devices and consumer health care

products. J&J looks forward to working with the government on the future regulation of consumer healthcare products, including Natural Health Products (NHPs) and over-the-counter (OTC) medications.

With Bill C-17*,* the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, Health Canada will be implementing significant changes to the *Food and Drugs Act* in the near-term to enhance post-market safety of therapeutic products and medical devices to enhance patient safety. J&J encourages the federal government to extend Health Canada's role in fostering patient safety by regulating the reprocessing and sale of single-use medical devices to Health Canada. This would allow for regulators to assess and monitor safety, effectiveness and quality of reprocessed medical devices.

J&J also urges the federal government to ensure that Health Canada has the required resources to sustain current regulatory activities and enhance its ability to undertake new regulatory responsibilities such as inspections and certifications, which will come into effect when Bill C-17 is implemented. Expansion of Health Canada's regulatory oversight role must not have a detrimental impact on the performance standards of existing regulatory activities for therapeutic products.

Beyond Bill C-17, J&J continues to support ongoing regulatory modernization initiatives to address other emerging regulatory issues which the current Food and Drugs Act does not address, such as biosimilars (subsequent entry biologics) and orphan drugs. J&J supports a modernized, risk-based regulatory system which (a) supports intellectual property protection, (b) is harmonized with leading international regulatory authorities, and (c) ensures that the overall regulatory burden is not excessive for both manufacturers and regulators while maintaining flexibility for special challenges (e.g., combination products).

Budget 2015 must ensure adequate resources to enable Health Canada to continue public engagement and consultation in order to ensure that the interests of all stakeholders, from patients to practitioners to manufacturers and distributors, are addressed in regulatory modernization initiatives.

Additional Issues

Priority*: CADTH Budget Flexibility*

J&J urges greater flexibility in how Health Canada resources are applied and utilized by the Canadian Agency for Drugs and Technologies in Health (CADTH), particularly as related to performance measures of the Common Drug Review's drug submission processes.

While CADTH is an independent, multijurisdictional agency, the federal government is one of the agency's largest funders and benefits from the information generated by the agency regarding the effectiveness and efficiency of health technologies. As such, the federal government has a clear interest in its efficient and effective utilization of public resources.

In March 2013, CADTH initiated a queuing process (backlog) for new drug submissions to the Common Drug Review (CDR). As a result, a backlog has been created at the CDR, creating uncertainty and delaying the availability of new therapies for many patients. These delays have been at least 5 months with a potential of being as long as 11 months (based on the number of drugs currently in the backlog).

CADTH has released a prioritization process to address this problem, allowing products to bypass the backlog based on clinical or cost-savings factors. In May 2014, CADTH also introduced a new user-fee model, with fees of up to $72,000 being charged beginning September 1, 2014 for the CDR. Importantly, unlike submissions to Health Canada, these fees are not currently linked to any clear performance standards or any policy that these additional resources will actually go to resolving the backlog.

These policy changes at CADTH have significant consequences for patients, whose access to new medicine is being delayed. The CDR is a mandatory requirement for access to new therapies through public drug plans.

J&J would encourage the federal government, as a key stakeholder and funder of CADTH, to direct the Agency to provide greater certainty to its drug submission processes to ensure that Canadian patients and their families may receive timely access to these innovative treatments. Any user-fees must be clearly linked to agreed-upon performance metrics and predictable review processes, consistent with the policies in place around user-fees elsewhere in the federal government.