

McNeil Consumer Health

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?

McNeil Consumer Healthcare recognizes that stabilizing world economies continues to be a significant challenge and that the government must use its resources carefully. However, it must also be recognized that despite this situation, Canada has performed well in comparison to many other countries around the world. For companies like McNeil, initiatives such as the government's Red Tape Commission have been an important part of ensuring stability for our business and the industry as a whole. That being said, there continue to be opportunities that we would like to work on with government such as regulatory modernization to ensure continued growth in Canada. In particular, McNeil continues to have concerns around the fact that consumer health products are evaluated under the same regulations as prescription drugs. While we support a strong regulatory system that ensures the safety of health products in Canada, submission requirements for non-prescription products should provide a level of regulation proportionate to the level of risk. McNeil Consumer Healthcare therefore recommends that Health Canada consistently regulate products with similar levels of risk and regulate non-prescription products and Natural Health Products within the same framework. We support the recently released Health Canada "Regulatory Roadmap for Health Products and Food" as it proposes to separate non-prescription drugs from the framework for prescription drugs. Given the limited resources that we as a country are facing, as well as the increasing costs of health care, implementing this recommendation would help avoid the over-use of those critical resources. Furthermore, we highly encourage the government's pursuit of global regulatory cooperation and alignment where possible in the area of consumer health products. Current inconsistencies with other international jurisdictions create a barrier to the Canadian marketplace and substantially affect trade and innovation. Specific measures with respect to recommended areas of regulatory cooperation will be outlined later in this submission.

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?

In today's global economy Canada's ability to grow and prosper does not exist in a vacuum. As noted in the questions, companies across the country are being affected by the economic situation in other countries all over the world. Now more than ever it is critical to recognize the importance of our external trade relationships. We applaud the government for the unprecedented effort it has been putting into developing trade relationships abroad, particularly with respect to CETA and TPP. However, trade agreements are not the only method by which we can encourage improved business practices and relationships across borders. Another important initiative undertaken by the government last year was the implementation of the Canada-U.S. Regulatory Cooperation Council. Regulatory cooperation can act as a catalyst to introducing modernized regulations for health products and reduce barriers to

introducing new products to the Canadian marketplace. McNeil Consumer Healthcare recommends one very important area of focus for the Council should be Good Manufacturing Practices (GMP). Currently, Canadian and American authorities conduct manufacturing facility inspections to ensure that health products are manufactured according to Good Manufacturing Practices. Despite U.S. and Canadian GMPs being equivalent, additional auditing requirements in Canada cause un-needed duplication of efforts by health authorities. In addition, Canadian regulations prevent health products from being shipped directly to Canadian customers from the US. Importing companies must ship products to their own warehouses, conduct duplicative testing and compile extensive and costly documentation before release in Canada consequently delaying shipment of product to customers. We recommend that a Mutual Recognition Agreement between Health Canada and the Food and Drug Administration for inspections of facilities manufacturing consumer health products be implemented. This would encourage business development in Canada and allow companies to focus resources in other more productive areas such as research and development.

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?

One of the major challenges that our health system will face in the coming years is the effects of our country's aging population. It is widely acknowledged that this growing demographic is going to place additional pressure on an already over-burdened system. It is imperative that all levels of government start looking at ways to reduce this impact as much as possible and come up with innovative ways to address rising costs and waning resources. One of the most overlooked, but significant ways that governments can address these difficulties is through the promotion of self-care. Self-care includes the decisions and actions people take to maintain and improve their health, treat minor ailments and manage chronic conditions. Before they consult with any health professional, enter any walk-in clinic or present to an emergency room, the vast majority of Canadians will have practiced some form of self-care to deal with most health concerns. Although a seemingly benign undertaking, the savings represented by more Canadians engaging in self-care before visiting a doctor are staggering. It is estimated that if just the doctor consultations associated with mild colds/flu could be avoided, it would save the healthcare system over \$98 million, or could free up family doctor access for ten percent of Canadians who currently do not have one. Even more astounding is the fact that while self-care measures accounted for almost 90% of all care for three minor ailments (headaches, colds and indigestion), the remaining 10% was being handled within the healthcare system at an estimated cost of \$2 billion. It is quite evident that even a small shift towards self-care in this demographic could account for significant savings within the health care system. McNeil Consumer Healthcare recommends that the Government of Canada seriously consider the use of tax policy to incent people to use self-care on a more proactive basis.

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?

Canada's productivity will be one of the driving forces behind our country's ability to compete on the international scene. A major part of addressing this issue will be reducing unnecessary burdens to trade through the coordination of regulatory approaches. By addressing these inefficiencies, particularly with our neighbour to the south, we open the door to increased opportunities for expansion by Canadian businesses. Although standards for efficacy and safety are very similar in both countries, over-the-

counter products imported from the U.S. are nonetheless required to be approved by Health Canada – a process that can take anywhere from 45 days to a full year. We recommend that both countries should enter into a mutual recognition agreement for the product registration process so that both countries could notify to a Monograph without the need to seek approval. This move would significantly facilitate trade and increase productivity by allowing for better use of resources.

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?

The sustainability of the Canadian Healthcare system is a challenge for business, communities and individuals. McNeil Consumer Healthcare supports efforts to focus on a sustainable health care system that embraces innovation and promotes positive health outcomes for patients. The federal government can help promote the best health outcomes by supporting innovation in healthcare through:

- Regulatory modernization including a separate framework for non-prescription drugs
- Supporting tax incentives which encourage self-care
- Ensuring that Canada's intellectual property regime is enhanced and competitive with other leading jurisdictions such as the European Union.

This will help maintain R&D in Canada. We continue to support the government's ongoing work in the reduction of Red Tape. The government should retain its excellent working relationship and partnership with companies such as ours. This partnership ensures the highest quality products are available for consumers while preventing the closure of plants which results in lost jobs for Canadians and drug shortages. McNeil Consumer Healthcare looks forward to continuing our productive relationship with the Government of Canada and working together to ensure Canadians have access to the most effective and safest products possible.