Submission by McNeil Consumer Healthcare
A wholly owned division of Johnson & Johnson Canada

To the

House of Commons Standing Committee on Finance

Consumer products bring savings to Canada's healthcare system

August 12, 2011

EXECUTIVE SUMMARY

McNeil Consumer Healthcare (MCH), a wholly owned division of Johnson & Johnson Canada (J&J), is pleased to participate in the House of Commons Standing Committee on Finance's consultation process in advance of the 2012 federal budget.

Our company is Canada's leading provider of consumer health products, with a strong commitment to enriching the health and safety of all Canadians. We develop products that keep people out of the emergency room for minor illnesses, therefore saving money, time and stress in our over burdened healthcare system.

J&J develops and provides Canadians with trusted brands such as Benylin, Tylenol, Motrin, Reactine, Nicorette, Nicoderm, Neutrogena, Aveeno, Band-Aid, Polysporin and Johnson's Baby products among many others.

J&J employs approximately 1,350 Canadians. Our Canadian head offices are located in Markham, Ontario and we maintain manufacturing facilities in Montreal, Quebec and Guelph, Ontario.

This submission focuses on current regulatory delays that impact our ability to grow our business in Canada and ensure that Canadian consumers have continued and reliable access to innovative consumer-based health products.

As outlined, unnecessary regulatory delays are resulting in increased economic uncertainty for our business, disadvantaging Canadian-manufactured products both domestically and internationally and have the very real potential to increase consumer product costs.

Of particular concern to J&J are:

- Regulatory harmonization;
- Notifiable Changes for over-the-counter products (OTC); and
- Current Health Canada approval processes for low-risk products.

1. REGULATORY HARMONIZATION

Inconsistent regulations between Canada and other jurisdictions can negatively impact the competitiveness of Canada's pharmaceutical industry, while jeopardizing consumer access to key over-the-counter healthcare products.

Health Canada recently consulted on a new guideline for labeling requirements that would result in unharmonious regulation between the Canadian industry and its international counterparts. Of particular concern to J&J included in the Draft Labeling Guidance document is the need to present final labels during submission review and the requirement for a nine-point font size.

The current creative label development process is based on feedback from the government just prior to product launch (30 days).

The need for these labels to be submitted prior to approval would result in an increased burden for the entire industry as would the expansion of the label review process, which would likely require additional government resources, effort and time.

In addition, should the 9-point font size guideline be implemented, it will change and complicate existing business processes for label development and lead to significantly expanded package sizes to accommodate a large amount of regulatory text.

As recommendations currently stand, there will be negative consequences to the economy; retailer; consumer and environment if implemented including:

- ***Reduced market competition / industry fragmentation:*** Recommendations included in the guidance document would create an unnecessary divide between Canadian-manufactured products and international products. Particularly, the need to present final labels during submission review has the potential to delay products reaching the market.

Recommendation

J&J recommends that changes outlined in the Draft Labeling Guidance document requiring presentation of final labels during submission review and the requirement for a nine-point font size ***not*** be implemented.

Benefits to government include:

Sustained economic recovery / achieving a balanced budget
Through the maintenance of current labeling requirements, the government can mitigate potential adverse economic effects associated with additional label reviews, including further demand on government resources and time, and unnecessary product packaging. In turn, the government can work to ensure regulations are consistent with other jurisdictions to improve competitiveness of Canadian-manufactured products.

2. NOTIFIABLE CHANGES

Notifiable Changes are changes that have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to its safety or effectiveness.

Since 2009, the average approval time for J&J-filed Notifiable Changes is 145 days (5 months). There have also been various unapproved filings for Notifiable Changes, taking an average time of 280 days and up to 375 days. The Health Canada current standard approval for Notifiable Changes is 90 days.

Due to long and unpredictable approval timelines, consumer access to important healthcare products has been backlogged in many cases.

In addition, unpredictable timelines has also resulted in product supply complications; negatively disadvantaging Canadian manufacturers and companies in both the global and domestic marketplace.

Recommendation

Through the current consultation on Notifiable Changes, J&J recommends that Health Canada reclassify manufacturing relocation and other minor Chemistry and Manufacturing changes that do not impact on product safety to annual notifications.

We fully support the government's indicated approach of eliminating Notifiable Changes.

Benefits to government include:

Sustained economic recovery / achieving a balanced budget

Through reclassification, the federal government will improve the competitiveness of Canadian consumer healthcare products. This will be achieved through consistent and reliable timelines for product supply.

In addition, there will no longer be backlogs in products being introduced to market. Removing current uncertainties will work to increase the dependability of these products and as a direct result, their value to Canadian consumers.

There will be a direct economic benefit for Canadian companies as they can rely on accurate and dependable timelines for products. This will increase company and product competitiveness globally; their ability to attract investment; and access for Canadian consumers.

3. PRODUCT MONOGRAPHS

With some exception, non-prescription products, by definition, represent low-risk healthcare products for minor and self-limiting ailments like a cough due to colds, headaches or seasonal allergies and should therefore not be regulated like high-risk pharmaceuticals.

However, Health Canada currently requires these products to go through the same process as pharmaceuticals, which consumes valuable time of industry and government. Currently, all products must undergo a labeling review, among other steps, and be issued a Drug Identification Number (DIN). This process can take between several months to a year and result in significant consumer product backlog.

Other jurisdictions avoid these unnecessary delays by regulating many over-the-counter "medicinal ingredients" through an OTC Monograph system, which outlines the conditions for marketing products with medicinal ingredients regarded as safe. In these scenarios, Manufacturers are free to go to market as long as they conform to the Monograph system.

Providing an independent framework for OTC's within the approval process would eliminate a significant portion of what is a duplicate approval process. Medications that would qualify to be listed or switched to OTC have maintained a clear safety track record on the Canadian market and have previously been approved through the drug approval process.

Recommendation

J&J recommends that Health Canada move to a 'management by exception' system based on post-market compliance, rather than expending time and effort at the pre-approval stage for all low-risk products with poor results and higher costs.

Benefits to government include:

Sustained economic recovery / taxation
Removal of this unnecessary red tape would significantly boost productivity and regulatory co-operation and reduce costs for businesses, consumers and government.

How to create quality sustainable jobs
In order to stabilize the economy and create jobs, it is important to work collaboratively with key trading partners to promote free and open trade and investment. However, one of the major obstacles to greater trade and investment with the U.S. and Mexico are product regulations that increase costs for producers and consumers and lead to delays. Through the adoption of a 'management by exception' system, these costs will be alleviated and improve trading opportunities for the benefit of the economy and Canada's global position in the marketplace.

Achieve a balanced budget
It is increasingly important to ensure Canadians are provided with the necessary consumer-based healthcare products to keep them out of the emergency room for minor illnesses; thus saving money, time and stress in our over-burdened healthcare system. Through the adoption of a 'management by exception' system for low-risk products, the government can help to ensure continuous and uninterrupted access to key consumer healthcare products critical to the treatment of minor illnesses and ailments. This will greatly reduce rising healthcare costs.

SUMMARY

J&J believes the recommendations set forth in this submission will work to reduce unnecessary regulatory delays while promoting economic recovery and future economic growth for the benefit of all Canadians.

In addition to helping the government achieve a balanced budget through taxation, job creation and economic stimulation, the recommendations will also reduce stress on Canada's over-burdened healthcare system by ensuring continuous and dependable access to consumer-healthcare products.