

2012 Pre-Budget Submission Brief

Submitted to the
House of Commons Standing Committee on Finance
by
Consumer Health Products Canada
on
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Executive Summary

Consumer Health Products Canada, the national association representing the consumer health products industry for over 110 years, is dedicated to advancing evidence-based self-care. Self-care is an important factor in the Canadian health care system and its role in disease prevention and health maintenance is an efficient primary public health resource. The sustainability of the Canadian health care system relies on Canadians becoming more involved in the management of their own health, which includes the responsible use of consumer health products. The majority Canadians use consumer health products, which include over-the-counter medications and natural health products at least several times a week. There is a strong demand to ensure that consumer health products available on the Canadian market are both safe and effective.

It has been more than a decade since the Minister of Health of the time accepted the Standing Committee on Health's 53 recommendations on the regulation of natural health products¹ and over eight years after the resulting *Natural Health Product Regulations* were passed. Health Canada has since made enormous strides in administering the regulations and licensing over 37,000 products for sale on the Canadian market. However, the time has come to enforce the *Natural Health Products Regulations* and give Canadians the assurance they have demanded for years- that products on the Canadian market are safe, effective and of high quality.

CHP Canada recommends that adequate funding be provided to Health Canada's Natural Health Products Directorate and the Health Products and Food Branch Inspectorate to implement a full compliance and enforcement program for the natural health products market, as defined in the *Natural Health Products Regulations*. This would ensure Canadians have ready access to natural health products that are safe, effective and of high quality, protect Canadians from being misled by unapproved product information, and build confidence in our regulatory and enforcement system.

¹ Standing Committee on Health, *Natural Health Products: A New Vision*, Public Works and Government Services Canada, Ottawa November 1998



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About Consumer Health Products Canada

Consumer Health Products Canada is the national industry association representing manufacturers, marketers, and distributors of consumer health products. The Association's members, who range from small businesses to large corporations, account for the vast majority of sales in Canada's \$4.7 billion market for consumer health products. Our members' sales are equally proportioned between natural health products and over-the-counter medications. Consumer Health Products Canada (formerly known as NDMAC) has been the leading advocate for the consumer health products industry for more than 110 years. Our goal is: "To build an environment that improves the opportunities for people to manage their own health through the responsible use of safe and effective consumer health products."

Canadian Self-care

From sunscreens to pain relievers, vitamins to allergy medicines, and toothpastes to acne treatments, consumer health products are used for the prevention, treatment, symptomatic relief, cure or risk reduction of diseases, injuries or chronic conditions that individuals can recognize and manage on their own behalf, either independently or in conjunction with health professionals.

Currently, 56% of Canadians use consumer health products at least several times a week and their demand will continue to rise as Canadians are increasingly committed to playing a greater role in the management of their own health. Surveys conducted for CHP Canada in 2005 revealed some important facts about Canadian self-care practices and perceptions: 44% of Canadians said that they had practiced more self-care than ever before in the previous 12 months, versus only 9% who said they had practiced less self-care; over 90% of Canadians agreed that if our health care system is to remain sustainable, it is more important than ever that governments provide them with the tools they need to practice responsible self-care; and 75% of Canadians agreed that if they had access to more clear and reliable self-care information, they could do a better job of managing their own health.

What these findings show is that Canadians are no longer content to be merely patients in the health care system. They are, in fact, the largest untapped resource available to the Canadian health care system. The value of self-care cannot be overstated. CHP Canada's recent unpublished data approximates 10 million cold sufferers saw a doctor in last year. If self-care support could lead just those with self-reported low symptom severity to practice responsible, evidence-based self-care instead of visiting a physician for the common cold, it could free up access to a primary care physician for approximately half a million Canadians and save the Health Care system approximately 98 million dollars.

Canadians demand safety and efficacy

A recent survey of 1000 Canadians² showed that consumers strongly prefer a pre-market approach for establishing the safety and efficacy of consumer health products in general and natural health products in particular. The large majority of Canadians agree that the government should ensure that there is evidence to

² Redfern Research, "Consumer views of Safety and Efficacy Issues Related to Consumer Health Products and Natural Health Products", July 2010



support health claims (95%) and the safe use (94%) of consumer health products before allowing them on the market. In contrast, there is only weak agreement (35%) that consumer health products should be assumed safe and action should only be taken against them once problems occur after they are on the market. Canadians hold similar views about safety and efficacy issues for natural health products and over-the-counter medications. Ninety percent of Canadians agree that both the safety and efficacy of natural health products should be demonstrated before those products reach the market. In contrast, only 31% agree that the safety of NHPs should be assumed unless problems emerge after a product is on the market. What these findings show is that Canadians demand that consumer health products and natural health products that are on the market are both safe and effective.

Issue Affecting the Consumer Health Products Industry

When Canadians across the country asked the House of Commons Standing Committee on Health to regulate NHPs to ensure product safety, quality and efficacy³, the government responded by promulgating the *Natural Health Products Regulations* in 2003. Health Canada's Natural Health Products Directorate was tasked with evaluating all new and existing natural health products on the Canadian market to ensure that there is appropriate evidence to support their safety and effectiveness and to ensure they are manufactured to a high standard of quality. In 2004, it was estimated that there were approximately 40,000 natural health products that would require product and site licenses from Health Canada to gain Canadian market authorization, thus creating an instant backlog of product and site license applications. Therefore, Health Canada developed transition provisions to provide a staged implementation and enforcement of the *Natural Health Products Regulations* to allow time for stakeholders to comply.

Health Canada's Natural Health Products Directorate has managed remarkably well in its implementation of the Standing Committee's recommendations. Since April 2011, Health Canada has issued over 27,000 product licenses representing over 37,000 products on the Canadian market, with thousands more product license applications that are currently under review. Therefore, in August 2010 Health Canada promulgated a regulatory solution⁴ to permit access to natural health products that meet a certain level of safety while Health Canada assesses product license applications awaiting a completed review. The *Natural Health Products (Unprocessed Product License Applications) Regulations* grant a temporary legal exemption (and number) to permit NHPs that meet certain safety criteria to be sold on the market until Health Canada completes its review and reaches a final licensing decision.

Health Canada made a promise to Canadians when the NHP *Unprocessed Product License Application Regulations* were passed that the Compliance and Enforcement Policy would be implemented immediately with a compliance promotion period of 4-6 months before the enforcement of the *Natural Health Product Regulations* would begin.⁵ Unfortunately, due to strong opposition to the *Natural Health Products Regulations* from some sectors of the NHP industry, Health Canada has constantly postponed the implementation of the new Compliance and Enforcement Policy.

³ Standing Committee on Health, *Natural Health Products: A New Vision*, Public Works and Government Services Canada, Ottawa November 1998

⁴ *Natural Health Products (Unprocessed Product License Applications) Regulations*, Canada Gazette Vol. 144, No. 19- May 8, 2010

⁵ *NHP UPLAR, Canada Gazette II, Vol. 144, No. 17, August 18th 2010. SOR/2010-171,*



Without enforcement of the *Natural Health Product Regulations*, this means that unlicensed products continue to be sold alongside legal products in many retail outlets. Unlicensed natural health products offer the consumer no guarantee regarding their safety, quality and efficacy. Moreover, the unapproved health claims may deceive consumers and create fraudulent impressions about the product's merit. Unlicensed products on the Canadian market also create an unlevel playing field for companies who choose to abide by the law. CHP Canada represents the evidence-based consumer health products industry with member companies who are responsible corporate citizens that go above and beyond what is required in the *Regulations* to ensure the safety, quality, and efficacy of the health products they sell to Canadians. The CHP Canada member companies took the necessary steps to come into compliance with the new regulations published in August, and specifically the Health Canada promised deadline for completion of the compliance promotion period.

This temporary buyer beware market that has been created due to a lack of enforcement is beginning to impact how consumers view natural health products. A recent Health Canada survey⁶ showing that consumer confidence in the safety, efficacy, quality and effectiveness of natural health products may be declining underlines the urgent need to finalize the implementation of the *Natural Health Products Regulations*. CHP Canada believes that the ongoing sale of noncompliant products is undermining consumer confidence in all NHPs and that full enforcement of the *Natural Health Products Regulations* will build consumer confidence in the long term.

CHP Canada is eagerly awaiting the announcement of a date scheduled in the near future to end the compliance promotion period and begin the enforcement of the *Natural Health Product Regulations*. After participating in stakeholder consultations on this topic, CHP Canada is concerned that the limited resources available for the compliance and enforcement of the *Natural Health Product Regulations* would be insufficient to appropriately mitigate the risks posed to the health of Canadians by the non-compliant natural health products that are currently available to Canadians on the marketplace.

CHP Canada's recommendations for the 2012 Budget

CHP Canada recommends that adequate funding be provided to Health Canada's Natural Health Products Directorate and the Health Products and Food Branch Inspectorate to implement a full compliance and enforcement program for the natural health products market, as defined in the *Natural Health Products Regulations*. This would ensure Canadians have ready access to natural health products that are safe, effective and of high quality, protect Canadians from being misled by unapproved product information, and build confidence in our regulatory and enforcement system.

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⁶ Ipsos Reid, *Natural Health Product Tracking Survey- 2010 Final Report*, Health Canada (2010)