Consumer Health Products Canada

Advancing evidence-based self-care

Pre-Budget Submission

Submitted to the

Standing Committee on Finance

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Executive Summary

- **The trend toward Canadians taking more control over their own health through self-care is associated with better health outcomes and lower health care costs.**

- **The growth of self-care with consumer health products (OTCs and NHPs) is hampered by financial disincentives and regulatory barriers.**

- **Making above-average OTC and NHP costs eligible expenses under the Medical Expense Tax Credit would, at a modest cost to the public purse, reduce overall health care costs and provide targeted tax relief for families and vulnerable Canadians.**

- **Prioritizing the development and implementation of separate regulations for OTC medicines would reduce government and industry administrative costs without affecting consumer health and safety.**

Consumer Health Products Canada (CHP Canada) is the national association representing the makers of consumer health products, including over-the-counter medicines (OTCs) and natural health products (NHPs). Consumer health products play an important role in self-care, which, in turn, is a vital component of our health care system.

As consumers have become increasingly savvy and proactive regarding their healthcare options, governments across the globe have been looking towards self-care as a viable approach to making healthcare systems more sustainable. In fact, the UK has evidence showing improved health and quality of life, greater patient satisfaction and significant reductions the use of health services, after it identified self-care as one of the four pillars of their National Health Service and instituted supportive policies[i]. In the United States, it has been estimated that for every dollar spent on consumer health products, $6 - $7 are saved elsewhere in the healthcare system, through reduced doctor visits, pharmacist dispensing fees and prescription drug costs[ii]. In Canada, several studies have demonstrated that switching medicines from prescription to nonprescription status creates net savings for the health care system and patients, through reduced doctor visits, pharmacist fees, lab tests, prescription drug costs and time away from work[iii],[iv].

The contribution that self-care makes to the health of Canadians and to the sustainability of their healthcare system faces significant obstacles in the Canadian policy environment. The most significant barriers concern the financial incentives for health behaviour inherent in a healthcare system that provides first-dollar insurance coverage for formal health care services such as doctor and hospital care and at least partial coverage for many prescription drugs, while leaving people to pay all self-care related costs out-of-pocket. A further financial disincentive to consumer health product use can be found in the differential tax treatment applied to prescribed versus non-prescribed (OTC and NHP) medicines. Prescription drugs enjoy zero-rated status under the Good and Services Tax and are eligible expenses under the Medical Expense Tax Credit (METC), which provides a direct incentive and also leads to the availability of tax-exempt employer-provided prescription drug plans (approximately nine out of ten Canadians have some form of prescription drug coverage).

A second obstacle in Canada lies in the regulatory environment for OTC medicines. OTC medicines are regulated under Part C of the *Food and Drug Regulations,* which is primarily constructed for the purposes of prescription drug regulation and contains many provisions that are inappropriate for lower risk consumer health products. The successful implementation since 2004 of separate regulations for NHPs, the *Natural Health Products Regulations*, has demonstrated that a regulatory regime appropriate to lower risk consumer health products can assure consumer safety while improving timely access to these products.

In view of the above, CHP Canada respectfully submits that the Standing Committee on Finance give consideration to the two following budget measures. The first recommendation addresses the theme of "supporting families and helping vulnerable Canadians by focusing on health, education and training. The second recommendations address two themes: 1) "Increasing the competitiveness of Canadian

businesses through research, development, innovation and commercialization;" 2) " Improving Canada's taxation and regulatory regimes".

Recommendation 1

> ***That annual purchases of consumer health products, including OTC medicines authorized for sale by Health Canada with Drug Identification Numbers (DINs) and NHPs authorized with Natural Product Numbers (NPNs), exceeding $190 be classified as eligible expenses under the METC.***

CHP Canada recognizes that the complete equalization of the financial incentives for self-care vis-à-vis the products and services captured by the *Canada Health Act* is neither desirable nor practical. The low cost of consumer health products makes them inherently more accessible to Canadians than insured services such as doctor or hospital care, and this accessibility maximizes the contribution that self-care makes to the sustainability of the Canadian healthcare system.

The METC is intended to provide tax relief to Canadians who face above-average health-related expenses. Making consumer health product purchases above the national average-per-taxpayer of $190 eligible expenses under the METC is entirely consistent with this objective, is affordable and fiscally responsible, provides targeted tax relief for families and vulnerable Canadians, and has the potential to relieve some of the upward pressure on government healthcare budgets. In addition to the direct tax relief for families that this measure would provide, making above average consumer health product purchases an eligible expense under the METC would give employers the option of providing their employees with insurance coverage for such expenses as a tax-exempt benefit, which has the potential to improve productivity and further reduce other health-related costs borne by both employers and governments.

The rationale for limiting the eligibility of consumer health product purchases to amounts exceeding the national average is threefold. First, this approach is consistent with the Government's historical approach of providing targeted tax relief to vulnerable Canadian families by focusing on those whose health needs cause them to incur above-average costs, as per the stated intent of the METC. While the low cost of most consumer health products makes them very affordable, many Canadians suffer from chronic conditions, such as allergies, minor arthritis pain or migraines that can be safely and effectively treated with consumer health products. In these instances, the annual costs can become significant and tax relief would provide meaningful support.

Second, by targeting above average users of consumer health products, this measure could enhance the contribution that self-care makes to the sustainability of our healthcare system and to economic productivity. For example, an individual with chronic allergies could incur related consumer health product costs of $350 a year or more. As there are prescription allergy products available for the treatment of these conditions, an individual with a strong prescription drug plan could have a financial

incentive to seek physician care and prescription drug treatment, resulting in far higher costs to government and his or her employer, but reduced out-of-pocket costs for the patient. This same allergy sufferer would have less incentive to seek that alternative if tax relief or the availability of insurance coverage lessened the financial burden of self-care with consumer health products.

Finally, limiting eligibility of consumer health product costs under the METC to those exceeding the national average makes this a modest and affordable form of targeted tax relief. CHP Canada estimates that making all consumer health product costs eligible under the METC would cost the government between $80 million and $100 million in forgone tax revenues. We estimate that limiting eligibility to above average costs would reduce this figure to less than $40 million. We note that any resulting increase in consumer health product sales would result in a partially offsetting increase in GST revenues, which currently stand at about $250 million.

Recommendation #2

> ***That Health Canada be directed to prioritize the development and implementation of distinct regulations for OTC medicines under the Food and Drugs Act such that these can be in place on or before July 1, 2016 and take immediate action where regulatory change is not required***

The current regulation of OTC medicines under Part C of the *Food and Drug Regulations* delays new product introductions, adds unnecessary costs and limits innovation. In recent years, there has been growing recognition from Health Canada that the regulation of OTC medicines needs to be separated from the prescription drug regulatory regime. The Minister of Health recently announced plans to hold public consultations on the development of a new regulatory framework for consumer health products that will include distinct regulations for OTC medicines. CHP Canada applauds this initiative and believes that it can address the aforementioned concerns without compromising, and even enhancing, patient safety. CHP Canada believes that the key features of an appropriate OTC regulatory approach must include:

- Removal of prescription drug-driven provisions, such as the requirement that novel combinations of established ingredients be treated as “new drugs,” that add administrative costs to both government and industry without enhancing the safety of low-risk OTC medicines;
- Provisions for manufacturers to attest to meeting regulatory standards for well-established low-risk products, that would significantly reduce product approval times and reduce costs to both government and industry;
- Development of labeling and product information requirements appropriate to consumer health products, rather than prescription drugs.
- A more consistent and efficient approach to controlling conditions of sale across Canada that would facilitate consumer access to Health Canada approved products and remove barriers to internal trade.

The development of a new regulatory framework for consumer health products is a resource-intensive initiative for Health Canada. However, given the long-term cost implications and consumer and economic benefits that this initiative will produce, CHP Canada believes that prioritization is justified. For example, in the 2012 Budget Plan, Health Canada was directed to modernize its approach to making changes to its prescription drugs list. The former regulatory approach to this list had been cited by CHP Canada as the source of delays in the introduction of new OTC medicines consisting of ingredients switched from prescription to non-prescription status. Canadians, in fact, had their access to these new medicines delayed by seven to eight years, by comparison to U.S. and U.K. residents. As a direct result of the subsequent change to an administrative approach introduced in 2013, Canadians will gain access to six new OTC ingredients switched from prescription status over the next six months. By contrast, under the old regulatory regime, only two such switches had taken place in the preceding five years. The healthcare and economic impacts of a modernized and appropriate consumer health product regulatory regime are demonstrable and immediate, and we respectfully submit that they deserve priority treatment.

In addition to the need for a new regulatory framework for OTC products, there are policy changes that Health Canada could implement immediately that could have significant benefits to the Canadian economy in terms of increased investments and job creation, at no additional cost to government. Specifically, when the *Natural Health Products Regulations* were implemented in 2004, they removed the requirement for manufacturers of products that had previously been regulated under the *Food and Drugs Regulations* to have "establishment licenses" and created a new requirement for "site licenses," which did not require Health Canada inspections. The result was that manufacturers selling products in foreign countries lost their ability to take advantage of Health Canada's Mutual Recognition Agreements (MRAs) with those countries, which made it easier to add Canadian facilities to their licenses and avoid duplicate inspections. As a consequence, a number of companies moved their manufacturing out of Canada, resulting in a loss of jobs and investments. A simple fix to this situation would be to allow manufactures of NHPs to decide if they want to hold establishment **or** site licenses. As establishment licensing requires more oversight by Health Canada than site licensing, there would be no health and safety concerns related to such a policy change and since establishment licensing is subject to cost-recovery, the cost to government would be borne by industry.

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[i] Department of Health, *Self-Care – A Real Choice: Self-Care Support – A Practical Option,* London 2005
[ii] Booz & Co., *The Value of OTC Medicine to the United States*, Washington 2012
[iii] Anderson et al, *The Economics of Self-Medication*, Queen's Health Policy, Kingston, Ontario 1995
[iv] Manga et al, *The Economics of Switching Drugs from Rx to OTC: The cases of H2RAs and Vaginal Antifungals*, University of Ottawa, 1999