Pre-Budget Submission

CHP Canada's recommendations for Budget 2019

Submitted to the House of Commons
Standing Committee on Finance

August 2018

Consumer Health Products Canada | Produits de santé consommateurs du Canada

Advancing evidence-based self-care
Pour l'avancement des autosoins de qualité

Consumer Health Products Canada (CHPC) is the trade association representing companies that make evidence-based over-the-counter (OTC) medicines and natural health products (NHP). The industry generates approximately $5.8 billion in GDP and supports almost 57,000 jobs in Canada. The products our members make contribute significantly to Canada's productivity and reduce demand on, and costs to, Canada's healthcare system.

In December, 2017, the Government's Advisory Council on Economic Growth released its third and final report which recommended an "agile regulatory that acts as a catalyst for investment and innovation" and recognized that "regulation also must be predictable, efficient, and consistent, so it is not a barrier to business investment, innovation, and ultimately, economic growth". The legislation and regulations that govern consumer health products are decades old and long overdue for a complete overhaul in order to catch up to the current environment.

While Health Canada is currently undertaking a comprehensive review of its consumer health regulations, results of that review, and the necessary changes that come with it, could be years away. As such, CHPC recommends a number of immediate and surgical amendments to the legislative regime that regulates our members' products, that will go a long way to breaking down barriers to growth and innovation for our sector in Canada.

Recommendation: Amendments to the Food and Drugs Act (F&DA) and regulations to allow sampling of consumer health products, and to recognize a broader scope of practitioners who can provide samples.

The F&DA prohibits sampling of all drugs, unless conducted under prescribed conditions by a limited list of health practitioners. The complete prohibition of direct-to-consumer sampling reflects an approach more consistent with the conditions of sale for prescription drugs than those for OTCs and NHPs. Moreover, the inability to sample consumer health products in Canada runs contrary to many public health initiatives, as it prohibits manufacturers from supporting actions such as distributing sunscreens at outdoor events.

In addition, the F&DA establishes that only physicians, dentists, veterinary surgeons or pharmacists may distribute samples of drugs. However, this limited list as set out in the F&DA has not kept pace with health care delivery and prescribing practices and, for example, prohibits nurse practitioners working in remote communities from distributing samples of drugs where access to a physician and medicines may be limited.

Recommendation: The Natural Health Product Regulations (NHPR) should be amended to limit the security packaging requirements to NHPs for internal uses only, consistent with the requirements for OTCs and with the level of risk imposed by these products.

For economic and trade reasons, and in the absence of a public health risk, it is important that Canada have security packaging requirements consistent with its major trading partners, in order to enable manufacturers to avoid the prohibitive cost of creating unique packaging configurations for the Canadian market. The *Food and Drug Regulations* exempt

dermatological/topical OTCs from their security (tamper-resistant) packaging requirements, as do the regulations maintained by the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration. The current inconsistences between NHP and OTC requirements in Canada create a burden for NHP companies to purchase additional packaging and labelling equipment for their Canadian topical NHPs, and this in turn raises the cost for Canadian consumers and undermines the competitiveness of these products on international markets.

Recommendation: Revisit the decision to exempt regulatory charges (user fees) the FDA from the requirements of the Services Fees Act (SFA) to ensure Parliamentary or central agency oversight.

The *Budget Implementation Act* 2017 replaced the former *User Fees Act* with the new SFA. However, at the same time, the F&DA was exempted from the SFA, and the Minister of Health was given authority to set fees by Ministerial Order. As a result, user fees charged for regulatory activities conducted under the FDA do not have to comply with the revised SFA to ensure accountability and Parliamentary oversight. CHPC believes that the decision to exempt the FDA was rushed through parliament without the necessary analysis and input from stakeholders at the time of the 2017 Budget and should be revisited to ensure public transparency and accountability remain paramount.

Since this change, Health Canada has exercised its right to set fees without Parliamentary or central agency oversight, and has done so in contravention of Treasury Board policies and in a non-transparent manner. The new user fees will more than double the burden on industry and were not accompanied by a full costing analysis, as required by Treasury Board policy.

CHPC can see no reason why the accountability and transparency required under the SFA should not apply to the user fee regime under the F&DA. A reversal of the decision to exempt the F&DA and return the authorities to set user fees back under the SAF should be seriously considered. At a minimum, changes to the fee regime must be subject to the Governor in Council regulatory process, to ensure the direct oversight of Treasury Board and strict adherence to Treasury Board policy on cost recovery and regulatory charges.

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