Consumer Health Products Canada

Pre-Budget Submission
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Executive Summary

Consumer Health Products Canada (CHP Canada) is the trade association representing companies that make evidence-based, over-the-counter (OTC) medicines and natural health products (NHP) – collectively known as "consumer health products". This is an industry which annually generates approximately $5.8 billion in GDP and supports almost 57,000 jobs in Canada. The value of our industry extends well beyond GDP and jobs, we make a vital contribution to Canada's productivity—that's because when Canadians use a consumer health product to manage their minor ailments we see reduced workplace absenteeism. Moreover, when Canadians use our products, they make an important contribution to reducing demand on and costs to, our primary healthcare system.

Everyday millions of Canadians use safe and effective consumer health products to manage their health and treat their minor ailments—such as coughs, colds, upset stomach, acute pain and seasonal allergies—and in doing so they get the results they seek and lead more productive lives. Using a consumer health product is one part of a broader suite practices we refer to as "self-care".

Statistically the majority of Canadians prefer to self-manage their minor ailments through the use of an OTC or NHP—this has helped place Canada's consumer health products market in the Top 10 globally for sales, despite a relatively narrow range of available self-care product options compared to other top 10 countries such as the US, Australia and the European Union.

The reason for this relatively narrow range of options is that the Canadian market lags most of our major trading partners when it comes to making prescription drugs available over the counter (Rx to OTC switching), the chief source of innovative new self-care products. The main barriers responsible for this are:

1) The regulatory pathway for Rx to OTC switch in Canada is complex, duplicative, costly and administratively burdensome; and,
2) Other countries provide regulatory incentives such as data protection that are lacking in Canada.

If the Government of Canada put in place modern, competitive policy and regulatory tools—similar to what exists in the United States, Australia and the European Union— the industry in Canada would have more favourable conditions for growth and would be able to offer Canadians a broader range of affordable consumer health products, leading to reduced healthcare costs and improved overall economic productivity.

Consumer Health Products Support Healthcare Sustainability and the Broader Economy

Safe, affordable, effective and available without a prescription, Canadians reach for consumer health products to manage their health and treat their everyday symptoms and ailments. Cold and allergy medicines, pain relievers, sunscreens, fluoridated toothpaste, antacids, and nicotine replacement therapies, these are just a small sample of the products our members make that allow people to live more productive lives.

When Canadians visit a pharmacy to obtain an OTC or NHP to treat their minor ailments they are practising "self-care." Self-care matters because when Canadians reach for a consumer health product they don't just get the results they seek; they make an important contribution to the sustainability of our health care system by avoiding unnecessary doctor visits. For example, while the vast majority of Canadians practise self-care, surveys have established that about 14% of Canadians visit a doctor to have their minor ailments treated. CHP Canada calculated that if just one in seven (16%) of those people who currently go to the doctor for colds, headaches/migraines or heartburn were to practise self-care instead, it would free up about three million doctor visits a year. That's enough to provide family physicians to 500,000 Canadians who currently don't have a family doctor.

The Problem: Outdated, overlapping federal and provincial rules limit self-care choices

Many of the OTC medicines Canadians use in self-care were once prescription drugs. Once prescribed pain relievers like Aleve® and Advil® and allergy medicines like Reactine® and Aerius®—to name a few—became available over the counter through a regulatory process called the "Rx-to-OTC switch".

Unfortunately, the Rx-to-OTC switch process in Canada performs poorly relative to our major trading partners. The way it works currently, Health Canada reviews all of the evidence submitted by a manufacturer, and makes a determination to approve the switch. Afterwards, the manufacturer navigates through a variety of different provincial approval processes that reaffirm the switch and decide where the product may be sold. This is called drug scheduling, and it determines if a product may be purchased from behind the counter through a pharmacist, or the front shop of the pharmacy, or through any retail outlet.

This overlapping and conflicting approach is unique to Canada—and while inevitably we reach the same conclusions as other countries on what products can be sold without a prescription—the switch process in Canada often leads to different provincial decisions regarding conditions of sale. This uncertainty and timely process for switch creates disincentives to innovative manufacturers in Canada and leads to long switch delays.

The impact of these 7 to 9 year switch delays are significant for consumers and governments. Take the case of proton pump inhibitors (PPIs) which are used to treat frequent heartburn. PPIs were switched in the U.S. in 2003, but weren't made available over the counter in Canada until

11 years later, in 2014. A 2017 report by the Conference Board of Canada estimated the switch of PPIs would generate annual savings of over $700 million through reduced doctors visits ($186 million), lower drug costs for employer and government sponsored drug plans and individual Canadians without coverage ($285 million), while improving productivity at work and reducing absenteeism ($239 million).

There is opportunity to resolve the overlapping federal and provincial regulations which govern the switch process in Canada. Health Canada is in the process of creating a new regulatory framework for all self-care products. The self-care products framework is the perfect occasion for Health Canada to work with its provincial partners to address the overlapping mishmash of federal and provincial rules that govern the switch process.

The Solution:

Health Canada should take a leadership role to work with provincial counterparts to integrate the drug scheduling into the federal process for approving drugs for sale without a prescription.

The Problem: Absence of Data-Protection for Self-care Products

Unlike the United States, Japan and the European Union, Canada offers no regulatory data protection for the evidence manufacturers submit in support of an Rx-to-OTC switch. The absence of any data-protection measures built into the switch process in Canada is a powerful disincentive for business to apply for switches, particularly in view of the complex and costly process described above, which only the innovator has to navigate. Second-entry products go through a simplified federal approval process and do not have to go through the drug scheduling process at all, meaning that they often make it to market within weeks of the innovator. This further contributes to a situation where Canadians have to visit the doctor for a prescription for medicines that are available elsewhere without such conditions. As we highlighted earlier, this imposes unnecessary demand and costs to our healthcare system, and it undermines worker productivity.

Because Health Canada has no mandate to consider the economic impacts of their role as drug regulator, any changes to the data protection regime under the *Food and Drugs Act* must be founded in Canada's international treaty obligations. Currently, the Government of Canada is subject to two international agreements that affect data protection: the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the North American Free Trade Agreement (NAFTA). Canada's approach to TRIPS and NAFTA establishes a period of eight continuous years of data protection for "innovative drugs". However, new consumer health products are usually introduced to the market after this eight-year period has expired. As a result, when companies submit data to Health Canada as a part of a switch application, they usually do so without any form of data protection.

Other countries have implemented alternative approaches to comply with international agreements while incentivizing growth for their consumer health products sector, in order to reduce overall health costs.

The Solution:

Modernize the *Food and Drugs Act*'s data protection provisions to be more consistent with protections that exist amongst Canada's major trading partners.

The Problem: Tax Treatment of Consumer Health Products Unfairly Punishes Self-care Choices

While health policy recognizes the importance of self-care to the health of Canadians and the sustainability of our healthcare system, tax policy treatment of consumer health products remains entrenched in a different era. Prescription drugs enjoy zero-rated status under the Goods and Service Tax (GST) and are eligible expenses under the Medical Expenses Tax Credit (METC). However, when a medicine switches to become a consumer health product, it becomes subject to GST and ineligible to be claimed under the METC.

As the Government of Canada undertakes its review of Canada's tax system to ensure it remains modern, fair, achieves policy objectives and incentivizes desired behaviours, we would encourage it to examine the current tax treatment of consumer health products and its impact on self-care, health and productivity.

Recommendation:

The Department of Finance or alternatively the Standing Committee on Finance undertake a review of the tax treatment of consumer health products, with a view to ensuring that measures are in place to incentivize self-care practices.

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Conclusion

Everyday, millions of Canadians use safe and effective consumer health products —many of which began their product life as prescription medicines—to self-treat their minor ailments. When Canadians reach for these products they don't just get the results the seek, in bypassing the doctor's office they contribute to the sustainability of our health care system and they are more productive in the workplace.

Other countries understand the impact these consumer health products have on both quality of life and overall economic productivity and have consequently developed policies and regulations to provide swift access to a greater range of safe and affordable medicines. Canada unfortunately, has seen the world pass it by.

Overlapping federal-provincial regulations and non-existent protections on data during switch applications, have led to an environment where Canada is increasingly seen as an uncompetitive market in which to operate. This just doesn't just cause harm an annual $5.8 billion industry, it has much wider implications that affect Canada's overall productivity. As we've described, in Canada we wait 7-9 years longer than our competitors to ultimately reach the same decisions. That means 7-9 years of doctors visits for a prescription for products that are used safely without such conditions elsewhere. This costs the health care system through unnecessary doctors visits, it imposes costs on private employer and government drug plans, it disadvantages low income Canadians without any drug plan coverage, and it erodes productivity through absenteeism. It further affects business decisions, and economic activity because Canada is not top of mind when global players make decisions on where to manufacture consumer health products or where to apply for product switches.

Our recommendations to streamline switch, build-in data protection to switch applications, and studying the effect of taxes on consumer health products have the potential to have far sweeping and beneficial impacts for Canadians, health care and the growth of the consumer health products sector.

We would welcome the opportunity to present these solutions in further detail before the Finance Committee as it moves forward with live-hearings in the Fall.