FOOD, HEALTH & CONSUMER PRODUCTS OF CANADA

FHCP

PRODUITS ALIMENTAIRES, DE SANTÉ ET DE CONSOMMATION DU CANADA

PASC

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SUBMISSION TO THE COMPETITION BUREAU

Digital transformation of self-care

FOOD, HEALTH & CONSUMER PRODUCTS OF CANADA

PRODUITS ALIMENTAIRES, DE SANTÉ ET DE CONSOMMATION DU CANADA

FHCP PASC

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1.0 Who we are

Food, Health and Consumer Products of Canada (FHCP) is the voice of Canada's largest manufacturing employer. The food, health, and consumer products sector employs over 350,000 Canadians across businesses of all sizes that manufacture and distribute the safe, high-quality products that are at the heart of healthy homes, healthy communities, and a healthy Canada.

2.0 Purpose of this submission

We value the opportunity to input into the Competition Bureau's market study[1] on Canada's health care sector. We applaud the Bureau's desire to support innovation in digital health through pro-competitive policies, and concur that this could lead to greater access and choice to health care products and services. Digital innovations in support of self-care in particular are especially relevant at a time when in-person access to health care professionals is constrained.

Rather than answer the discussion questions in the order below, the submission is structured to provide separate analyses supporting the five recommendations for consideration as summarized in Section 3.0 of this report. For convenience, the discussion questions have been annotated below to highlight each section of the report where these questions are primarily addressed. This submission is intended to facilitate a starting point for discussion with the Competition Bureau on the opportunities to improve digital access to self-care products and services.

Discussion Question 1) Rules that limit choice and virtual access to self-care products (Addressed in Section 4.1)

> Are there ways that policies can better support innovation, choice and access to digital health care solutions? For example, do specific rules unnecessarily impact the ability to offer virtual products and services to Canadians? Please explain.

Discussion Question 2) Other barriers limiting innovation and virtual access to self-care products (Addressed in Section 4.2)

> What other barriers are impeding Canadians' access to virtual care and restricting innovation and choice in the health care sector? Can these barriers be reduced—and, if so, how—in order to facilitate the entry and expansion of digital solutions?

Discussion Question 3) Measures in other jurisdictions to encourage innovation, increase choice and enable virtual access to self-care products (Addressed in 4.3)

> What measures have other jurisdictions taken to improve access to virtual care? How have barriers to innovation and choice been eliminated, while balancing legal and regulatory requirements in the delivery of digital health care solutions? Can similar measures be adopted in Canada? Why or why not

Discussion Question 4) Impacts of the pandemic on self-care (Addressed in Section 3.4)

> What impact has the COVID-19 pandemic had on innovation and choice in Canada's health care sector, and on Canadians' ability to access health care virtually? Have any barriers hindered the adoption of digital solutions in response to the COVID-19 pandemic? Please explain

3.0 Executive summary

[1] Competition Bureau. Share your views on how to support innovation and choice in Canada's health care sector (July 2020) https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04547.html

The pandemic represents an inflection point for Canadian self-care. Key themes have emerged demonstrating importance of self-care as an important first step in containing the spread of the virus and preventing strain on the healthcare system. The role of health literacy in informed decision making highlighted the need to support Canadians as they navigate increasingly complex information environments towards achieving better health outcomes. Lastly, the rapid rise of digital forms of sale has accelerated a decade worth of growth in online purchasing in a short period of time. Reflecting on these themes, there is an opportunity to develop policies to encourage the development of innovative, digital tools to support better informed use of self-care products in a digital health care setting.

Canadians need to be able to access all the over-the-counter drugs they need to maintain and improve their health through digital means, while also avoiding any unnecessary doctor visits. Canadians were already purchasing over-the-counter drugs online before the pandemic, though not as often as many other products. The demand for digital access has increased substantially, as visiting local bricks and mortar pharmacies is not possible for those self-isolating and not preferable those seeking to avoid potential exposure. This online route for obtaining products has grown somewhat since the pandemic, exposing both gaps and barriers arising from how these products are regulated with respect to their conditions under which they must be sold.

Canada has a complex and outdated regulatory environment for over-the-counter drugs. The federal *Food and Drugs Act* wasn't developed with the future digital world in mind. On top of these federal requirements, there is a overlapping and inconsistent provincial regulatory regime determining how over-the-counter medicines (OTCs) must be sold ("conditions of sale"). After the Federal regulator approves a product for use without a prescription, additional requirements are imposed provincially restricting how OTCs can be made available for sale. In addition to the inherent complexity, inefficiency and inconsistency arising from these overlapping regulatory regimes, the status quo imposes several barriers to advancing the role of digital health in self-care:

- The current regulations governing conditions of sale focus on the physical *place* of sale and associated professional standards, not addressing how *conditions* of sale could be met digitally..
- The legal authorities for the provincial regulation of the conditions of sale for OTCs are anchored in pharmacy legislation, which is structured for the regulation of the pharmacy profession, not health products. The self-regulating colleges of pharmacy have no real mandate to regulate or even explore the potential of non-pharmacy digital tools for supporting informed self-care product use;
- The conditions of sale that apply to particular products are not nationally harmonized, neither in bricks & mortar settings nor online, leading to inconsistent product access for Canadians across the country, and;

The main way Canadians have historically obtained over-the-counter drugs (OTCs) has been through visiting bricks and mortar pharmacies where they can read the physical product label and ask a pharmacist for help if they needed to decide which product is best for them. Federal and Provincial regulators have primarily viewed product labels and the availability of a pharmacist as the only ways to help inform safe selection and use. This antiquated regulatory approach ignores the opportunity to drive better informed use of OTCs by leveraging digital tools in the product selection process.

Pro-competitive policies are needed to encourage the development of innovative digital tools to support better informed use of over-the-counter drugs in a digital health care setting

Providing access to OTC drugs using digital health information technology will increase the ability of Canadians to take advantage of virtual self-care and improve health outcomes. Federal leadership is needed to help drive the development of modernized rules supporting digital health access to OTC products. Currently, there is no interest in updating this approach and harmonizing requirements among provincial decision makers, who are rightly focused on matters related to the advancement of pharmacy practice.

The recommendations below summarize how the Competition Bureau can work with the Federal government to advocate for policies to eliminate barriers to accessing OTC drugs through digital means and introduce policies that can foster the entry and expansion of new and more efficient ways for Canadians to obtain a greater variety of innovative OTC drugs online. These recommendations would further build on the numerous policy drivers for federal leadership in this space, from Parliamentary Committees[2], the Canadian Free Trade Agreement[3], and Regulatory Forward Plan[4] commitments for regulatory modernization, harmonization and federal integration of provincial conditions of sale to support better informed use of OTC drugs.

Recommendations:

1) **The Competition Bureau should advocate that Health Canada:**
   a) **Lead the federal integration of nationally harmonized provincial drug schedules into the regulatory renewal initiative for over-the-counter drugs known as the Self-Care Framework;**
   b) **Lead the modernization of the conditions of sale for over-the-counter drugs creating a federal regulatory backdrop that fully leverages electronic labelling and other digital tools, and enables Canadians access to over-the-counter drugs through digital means in an environment that can be consistent nationally;**
   c) **Introduce regulatory incentives to encourage industry to develop innovative tools to support informed selection and access to all over-the-counter drugs through digital means;**
   d) **Establish policies to encourage digital health information sharing between institutions and with third parties, within a consistent national privacy protection framework to boost innovation in digital health;**
2) **The Competition Bureau should advocate that the Treasury Board advance the development of economic mandates for all federal regulators and require a competition assessment when developing policies and regulations.**

[2] HESA, Pharmacare now: Prescription medicine coverage for all Canadians (2018) https://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-14
[3] Regulatory Reconciliation and Cooperation Table Work Plan 2 https://www.cfta-alec.ca/wp-content/uploads/2019/06/RCT-2019-2020-Workplan-List-of-Measures-Final-May-29-2019.pdf
[4] Health Canada, Regulatory Forward Plan 2019-2021. Self-Care Framework https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/self-care-framework.html

4.0 Self-care context in Canada

4.1 What is self-care

Self-care is the treatment and actions Canadians take every day to maintain and promote their health. It includes everything from healthy lifestyle choices and disease prevention to treatment of minor health ailments to management of chronic disease. The concept of self-care is simple- the better Canadians are equipped to take care of themselves, the less need direct support they will need from our health care system. A sustainable health care system has a balance between professional care and self-care.

4.2 Impact of self-care on the health care system

Canadians are increasingly interested in taking more control over their own health. In a 2015 survey, 77% of Canadians said they would rather treat their minor ailments themselves than see a doctor, and 49% reported that they were more likely to practice this form of self-care than they were five years before. The 2015 survey also explored the varying balances between the number of Canadians who practice self-care and those who consult a doctor, for a variety of ailments. The effect on health care resources is significant with even a small shift in the balance between self-care and professional care for coughs and colds, headaches and heartburn/indigestion. A shift to self-care for just 2% of the Canadians who suffer from these three ailments would reduce the primary care burden by more than 3 million doctor visits annually. FHCP estimates that this would free up sufficient physician resources to allow an additional 500,000 Canadians access to a family doctor (Fig 1).

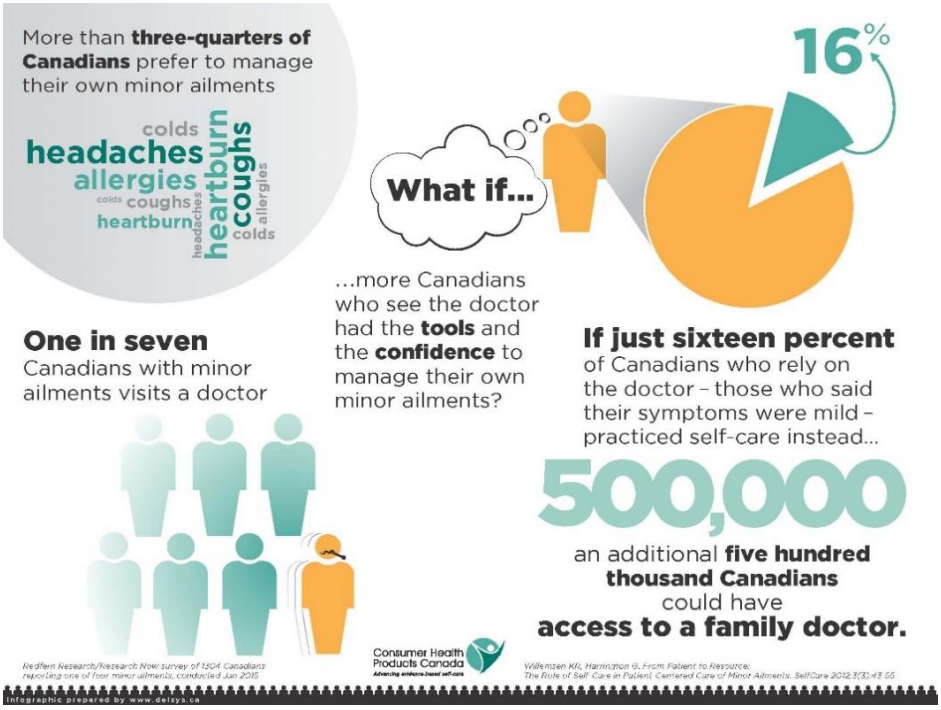

Figure 1. Impact of Self-care on the Canadian health care system

4.3 Impact of self-care innovation on the health care system and the economy

The main driver for growth of the $6 Billion dollar per year consumer health product industry is when prescription drugs are switched to OTC status (Rx-to-OTC switches, creating new options for Canadians to practice self-care. The majority of the top Canadian OTC brands were Rx-to-OTC switches, such as Advil™, Voltaren™, Aleve™, Zantac™, Reactine™, and Canesten.™ Switching

innovative OTCs from prescription status can not only generate health care system savings, but economic benefits as well. A study by the Conference Board of Canada on the value of switch showed that one billion dollars could be freed up in the Canadian healthcare system and broader economy by switching just three categories of products[5] (Figure 2). The three prescription medication categories were (1) proton-pump inhibitors (PPIs) to treat frequent heartburn/indigestion (which has already seen some medicines switched in Canada) and two other potential switch candidates (2) oral contraceptives and (3) erectile dysfunction medicines.

Figure 2: Summary of results from the Conference Board of Canada report on the value of Rx-to-OTC switch

Stakeholder	PPIs	Oral Contraceptives	Erectile Dysfunction	Total
Governments (cost of primary care visits + public drug plan coverage)	$382.4 M	$100.1M	$41.4M	$523.9M
Employers (productivity)	$239.1M	$145.4M	$45.1M	$429.6M
Private drug plans	$169.8M	$31.0M	$19.8M	$220.6M
Additional costs to individuals	($81.4M)	($54.3M)		($135.7M)
Total savings	**$709.9 M**	**$222.2M**	**$106.2M**	**$1.03 B**

The total savings would come from reduced drug costs, approximately 6.6 million fewer doctor visits and improved productivity (reduced time away from work for doctor visits for all three medications and for PPIs, in particular, reduced absenteeism and reduced impact of symptoms on work productivity). While switches transfer costs from governments and payers to consumers, they actually lower costs for Canadians who need it most. Individuals with the best drug plan coverage would incur additional costs, while those with poorer or no drug coverage would have a decreased cost burden as non-prescription products are made available at lower costs.

The choice of self-care products—in large part driven by safe Rx-to-OTC switch—is limited compared to other countries such as the US, Australia and the European Union. The main barriers to switch are the complex, duplicative, and costly regulatory process for switching in Canada, as well as the lack of data protection for innovators—something offered in other countries, which is outlined in section 4 of this report.

4.4 Impact of the pandemic on Canadian self-care

The importance of self-care recently became more apparent as it was a key component of Canada's, and many other countries', approach to battling COVID-19. Faced with the rapid emergence of this highly contagious and deadly virus, leaders and health authorities called on people to stay home. This has resulted in the management of less serious cases of the virus and a wealth of other health conditions at home, as much as possible. This was necessary to prevent COVID-19 spread and reduce burden on a health care system that needed to focus on critical cases of COVID-19, emergencies, and health conditions requiring immediate attention. Moreover, self-care behaviours such as social distancing,

[5] Conference Board of Canada Value of Consumer Health Products: The Impact of Switching Prescription Medications to over-the-counter (2018) https://www.chpcanada.ca/sites/default/files/files/8681_EcoImpactsRxTtoOTC_RPT.pdf

mask-wearing, hand hygiene, and following advice of public health professionals will be far more important to the outcome of the pandemic than any other intervention, until a safe and effective vaccine is available.

In a May 2020 survey, 2000 Canadians were asked about the management of their health before and during the COVID-19 pandemic, including their self-care activities and viewpoints [6]. Approximately half of survey respondents missed an in-person appointment with a doctor due to the COVID-19 pandemic response measures. Of those, more than half practiced a range of self-care activities—19% of respondents took care of the problem themselves, another 19% used virtual care services, and 16% sought a pharmacist's advice. More than half of those who managed their health conditions themselves during the pandemic were satisfied with the results, and more than half of those who used virtual care would do so again even after the pandemic is over. As a result, more than 50% of Canadians are now saying that they are more comfortable practicing self-care at home.

Additionally, Canadians are seeking more information about their health, with approximately 40% saying they have looked for more information on how to protect themselves from COVID-19 as well as treat common ailments they experienced since the pandemic response began. The main sources of that information included TV or radio news, provincial governments, family members, the federal government, and friends, with around 1 in 4 Canadians seeking information from health professionals, and 12% using Telehealth or other call-in services. On government information about the pandemic, an average of more than 90% of respondents find information from all levels of government – federal, provincial, and municipal – on the outbreak useful. At the same time, 64% say that, in general, information about COVID-19 has been inconsistent or confusing. Taken together, Canadians are navigating a complex information environment. Despite high self-reported health literacy compared to Europeans, Canadians are equally challenged to judge the reliability of health information, other than information they get from their physician or pharmacist[7].

Overall, the COVID-19 pandemic increased the interest of Canadians in their health and motivated them to practice a range of self-care activities, including virtual care and consultation with pharmacists and physicians. The pandemic has reinforced the importance of responding to the needs of Canadians who want more support and information to continue managing their health in the future.

[6] Redfern Research, Self-Care Information and behaviour among Canadians during the COVID-19 pandemic (May 2020) https://www.chpcanada.ca/wp-system/uploads/2020/07/Redfern-Research-Self-care-During-Pandemic-Report-July-13-2020-FINAL.pdf
[7] Redfern Research, Health Literacy Survey (July 2017)

4.4.1 Impact of the pandemic on virtual care

The pandemic was the driver to break down long standing barriers to virtual care. These barriers included technical interoperability of the digital tools used, navigating the legal patchwork of privacy rules across the country and different medical practice requirements and billing structures in each province. The pandemic forced the need of virtual health care and governments rapidly responded to remove these barriers, accelerating roll out and implementation. With the new opportunity to engage in virtual health care services, Canadians interest in these tools increased to replace in-person visits. By the end of April 2020, the proportion of virtual (video, phone and to a lesser extent email) visits increased to 60 per cent from less than 20 per cent prior to COVID-19[8]. Canadians satisfaction level with virtual visits were high, only marginally below satisfaction levels with in person visits. [9]

4.4.2 Impact of the pandemic on innovation and choice of self-care products

The pandemic has revealed how important self-care products are to Canadians, supporting their efforts to care for themselves and their loved ones at home. The consumer health product sector tied with the food and beverage sector experiencing the greatest increase in consumer demand across all commodities as Canadians stocked up and prepared for self-isolation. During the month of March, when retail experienced the greatest surge in demand as a result of the pandemic, consumer health products and food/beverages both experienced a 42% growth in sales, far exceeding growth of other commodity types[10]. Certain self-care product types experienced more growth than others, like demand of hand sanitizers increased over 700%, and cough cold products increased over 200%[11]. The Public Health Agency of Canada recommends Canadians stock up and have certain OTC medicines on hand when self-isolating[12].

Canadians also turned more to online shopping in general. In April 2020, year-over-year total retail sales were down 32.8%, e-commerce retail sales were up 120%, taking their share of total retail sales from 3% to 9.5% over that period.[13] Notably, while pure-play online retailers' (e.g. Amazon, EBay, Etsy) sales were up 70% year-over-year, the online sales of bricks and mortar retailers (e.g. The Bay, Home Depot, Walmart) soared more than 350% for the same period. Despite this significant increase in e-commerce in general throughout Canada, the consumer health product sector did not experience this growth. Before the pandemic, the proportion of sales of OTCs from FHCP members' e-commerce channels "rounds to zero".[14] While companies have some limited growth of e-commerce sales of Canadian OTCs, it has been limited to certain products and certain retailers, falling short of its full potential[15]. In contrast, the US OTC market experienced a 35% growth total e-commerce within the health department. In the US, 41% of consumers are buying more health products online than they used to[16], compared with only 14% of Canadians[17]. In the US, online purchases actually surpassed in-store in several categories (internal analgesics, toothpastes, gastrointestinal, hand sanitizers and first aid

[8] Green, M. *Virtual Care is the Future of Health Care Delivery in Canada.* https://www.hilltimes.com/2020/05/10/paid-content-virtual-care-is-the-future-of-health-care-delivery-in-canada/247763 (accessed May 20, 2020).
[9] Canadian Medical Association, Abacus Data, What Canadians think about virtual health care (May 2020) https://www.cma.ca/sites/default/files/pdf/virtual-care/cma-virtual-care-public-poll-june-2020-e.pdf
[10] Statistics Canada, Retail commodity Survey, Retail Sales https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2010001601
[11] Statistics Canada, Canadian Consumers Prepare for COVID-19 https://www150.statcan.gc.ca/n1/pub/62f0014m/62f0014m2020004-eng.htm
[12] Health Canada, Be Prepared for COVID-19 (Infographic) https://www.canada.ca/en/public-health/services/publications/diseases-conditions/covid-19-be-prepared-infographic.html
[13] Statistics Canada, Retail e-commerce sales- Unadjusted https://www150.statcan.gc.ca/n1/daily-quotidien/200619/t004a-eng.htm
[14] Personal communication, CHP Canada Board of Directors
[15] Personal communication, CHP Canada members
[16] Coresight Research Survey on the impact of Coronavirus on Consumer Behaviors, April 8, 2020
[17] Redfern, Self-care Information and Behavior Among Canadians During the COVID-19 Pandemic (2020)

antiseptics), driven by early stock ups and likely due to out of stocks in retail[18]. However, these out of stock situations at retail may not have been as prevalent in Canada, which is only one factor contributing to this limited e-commerce growth of OTCs in Canada in addition to the barriers discussed within this report.

Manufactures applied a number of different strategies to respond to this increased consumer demand throughout the pandemic. For example, some companies repositioned manufacturing lines and ramped up production of existing manufacturing lines to meet consumer demand. Many rationalized their existing product offerings to streamline the manufacturing process to increase output. This has had a temporary, and in some cases permanent, decrease in product choice. Moreover, resources dedicated to developing innovative products, such as Rx-to-OTC switch products, may have had to be redeployed to execute pandemic response strategies, which could have a lasting impact limiting innovative self-care product options for Canadians.

5.0 Recommendations

This section of the report outlines each of the five recommendations for consideration by the Competition Bureau identifying the specific regulatory or policy barrier, legal considerations and international best practices.

5.1 Drug Scheduling process and structure undermines virtual access to OTC medicines

Both the Federal and Provincial/ Territorial governments play a role in how over-the-counter drugs are regulated. The Federal government (Health Canada) decides which health products are approved for sale in Canada, based on a review of evidence on safety, quality and efficacy. They also decide whether this product can only be sold pursuant to a prescription from a provincially authorized prescriber. When Health Canada approves the "switch" of a product from a prescription drug to non-prescription status, the Prescription Drug List (established under the *Food and Drugs Act*) is amended to enable the ingredient at a certain dose, route of administration or for a specific use, to be made available without a prescription.

Despite the fact that the *Food and Drugs Act* provides clear authority over conditions of sale for all health products, Health Canada leaves the most important decisions in this area to the provincial and territorial governments. Provincial/ Territorial governments, through regulations associated with their respective Pharmacy Acts, re-assess the need for a prescription requirement and consider further conditions of sale, through drug scheduling (Figure 3). For example, Provincial/Territorial pharmacy regulatory authorities determine whether:

- An over-the-counter drug is required to be sold pursuant to a prescription (Schedule I)
- An over-the-counter drug can only be sold only through direct pharmacist intervention and are located behind the pharmacy counter (Schedule II), or;
- An over-the-counter drug requires a pharmacist to be present and must only be sold in a pharmacy (Schedule III), or;
- An over-the-counter drug can be sold in any retail outlet (Unscheduled).

[18] IRI e-Market Insights and IRI Market Advantage Date 6 weeks ending March 29 2020

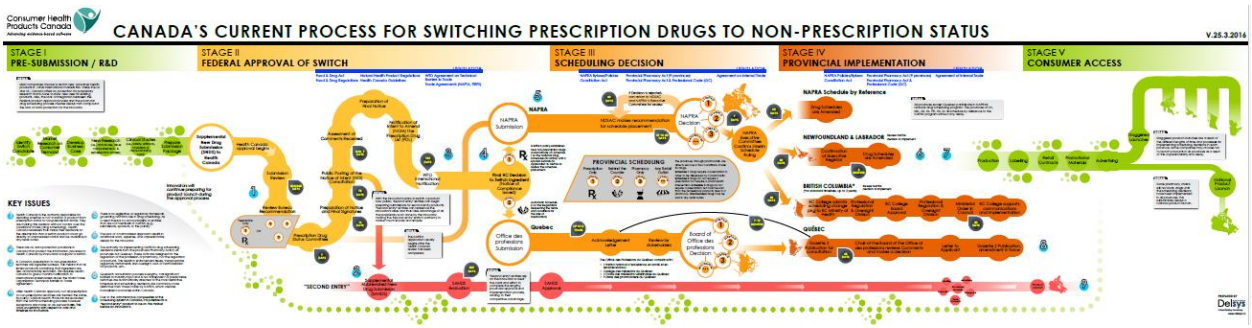

Figure 3: Graphic of the current Federal and Provincial switch and scheduling process

The National Association of Pharmacy Regulatory Authorities (NAPRA) was established in 1995 in part to achieve national harmonization of the conditions of sale for consumer health products under the National Drug Schedules (NDS). Most Provincial/Territorial Pharmacy Acts "schedule by reference" to the NDS, where by those decisions on the placement of sale are automatically adopted. However, British Colombia, Newfoundland and Labrador require additional regulatory processes to adopt NAPRA's National Drug Schedules, and Quebec maintains an independent process.

5.1.1 Legal underpinning of the duplicative and overlapping federal/provincial process for setting the conditions of sale for OTC medicines creates a market restrictions and gaps in enforcement

Canada is not the only jurisdiction that manages a federal/provincial overlap in regulating the conditions of sale of over-the-counter drugs, but we are the only jurisdiction that manages these conditions through Provincial/ Territorial Pharmacy Acts and Regulation and where the decision making process isn't streamlined into the federal approval process. The separation of the federal and provincial jurisdictions in the decision making structure for determining the conditions of sale for OTCs in Canada is creating market restrictions that may be unnecessary and is resulting in gaps in enforcement.

Market restrictions

Market restrictions occur when conditions are placed on the supply of a product that constrain the customer in terms of where the product must be marketed or exacts a penalty of any kind from the customer if the product is supplied outside of a defined market. While these practices are not illegal in themselves, they may become a cause for concern if they are found to be unnecessary and have caused, a substantial lessening of competition in a market. As Health Canada does not control the provincial decision-making process, reviewers approve Rx-to-OTC switches that are deemed safe and effective for self-care based on the assumption they will be made available for general retail sale. The added market restrictions imposed by Provincial/Territorial governments may not necesasrily be aligned with Health Canada's standpoint to ensure safe and effective use. There have been examples where NAPRA has blocked Rx-to-OTC switches. This occurred once in 2009 with naproxen, and twice in 2014 for omeprazole and 1% topical hydrocortisone. In these scenarios, NARRA's National Drug Advisory Committee (NDSAC) recommended that the product remain on Schedule I (prescription status) if the product was in certain pack sizes even though no such limitation was imposed by Health Canada, or by Quebec. In Quebec, Rx-to-OTC switches are automatically placed on Schedule II, enabling access without a prescription in accordance with a pharmacist consultation.

Gaps in enforcement in retail and online

Provincial Pharmacy Acts are intended to govern the practice of pharmacy. Manufacturing products is no longer a main focus of their scope of practice of pharmacists[19]. They originally played a significant role in product manufacturing decades ago, which no longer reflects the industry reality. Provincial/ Territorial Pharmacy Acts may no longer be the most appropriate instruments for product regulation, creating gaps in enforcement. Provincial Pharmacy Regulatory Authorities enforce the National Drug Schedules (NDS) within the scope of powers attributed by their Pharmacy Acts and Regulation. However, in 2011, the Ontario College of Pharmacists and the Saskatchewan College of Pharmacists indicated to that it may be limited in its ability to enforce the NDS outside of a pharmacy setting (ie. health food store). The Colleges may have received direction from the Solicitor General such that prosecutions cannot be brought against retail stores that sell Schedule I, II or III drugs that are in contravention of the law, which restrict the sale of those products to pharmacy. This gap in enforcement capabilities and jurisdiction requires federal integration and oversight across the different sections of the Canadian retail environment, both online and through bricks and mortar locations to ensure a consistent approach to compliance and enforcement. Moreover, a recent court challenge [20] determined that professional colleges regulate the practice of their profession in the province, and they cannot limit the commercial sale of products under the scope of practice to other jurisdictions through e-commerce, as limiting a provincial profession to distribute products within their province only would create a monopoly within a province. Digital product access provides a means for Canadians to obtain products across jurisdictional borders, which needs to be paired with a federal mandate for oversight so that conditions of sale can be consistently enforced across Canada. Self-regulating pharmacy colleagues have no real mandate to regulate or even explore the potential of non-pharmacy digital tools for supporting informed self-care product use, and therefore federal leadership is needed to drive policy innovation.

International Best-Practice

In Australia, the federal/provincial overlap in determining the conditions of sale is managed by the Federal regulator applying transparent and consultative process with state and territory officials[21]. A committee of experts appointed by state and territory representatives make recommendations to the Federal regulator on the conditions of sale of a particular product. The final decision is ultimately the responsibility of the Federal regulator, as the decisions take effect through the force of federal regulation. Decisions are implemented in a harmonized approach across the country, although states and territories do reserve the right to implement a different decision to accommodate local circumstances if they can defend this decision. The net effect is that all decisions on conditions of sale remain harmonized throughout Australia. This federal legal underpinning for conditions of sale in Australia creates a clear mandate to enforce these requirements retail and e-commerce channels.

Proposed solution

Health Canada is currently addressing switch and scheduling issues through the *Self-care Framework*[22] and has described their vision for an integrated governance approach to self-care health products that brings together the federal Health Portfolio, the provincial and territorial governments and relevant

[19]Canadian Pharmacists Association, Pharmacist's Expanded Scope of Practice in Canada, June 2020 https://www.pharmacists.ca/pharmacy-in-canada/scope-of-practice-canada/

[20] College of Optometrists of Ontario v. Essilor Group Inc., 2019 ONCA 265 https://www.canlii.org/en/on/onca/doc/2019/2019onca265/2019onca265.html

[21] AHMAC, Scheduling Policy Framework for Medicines and Chemicals, Version 1.0 January 2018 https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemical

[22] Next Steps for the Self-Care Framework , 2019 https://www.canada.ca/en/health-canada/services/self-care-framework.html

stakeholder associations to address point of sale issues for these products. This is the first time in over fifty years a comprehensive regulatory modernization approach has been proposed for over-the-counter medicines. NAPRA is questioning its ongoing role in the National Drug Schedules for a variety of reasons, including: the lack of a legislative and regulatory framework to underpin its role; the lack of an adequate consultative and policy capacity to maintain the National Drug Schedules in a changing healthcare and industry landscape; and, concerns about the ability to enforce the drug schedules in non-pharmacy settings. As a part of the Self-Care Framework, FHCP is working with Health Canada and provincial pharmacy regulators to integrate the drug scheduling process within the federal drug approval process.

Recommendation 1 a) Lead the federal integration of nationally harmonized provincial drug schedules into the regulatory renewal initiative for over-the-counter drugs known as the Self-Care Framework

5.1.2 Lack of nationally harmonized conditions of sale results in inconsistent product access for Canadians

Canada is not the only jurisdiction that imposes additional conditions of sale in the pharmacy and retail environment, but we are the only jurisdiction where the decisions are not integrated into the federal product approval process, resulting in a lack of national harmonization.

The provincial drug scheduling process leads to uneven access to consumer health products, from province to province, especially to new products that have had the prescription requirement removed federally (Rx-to-OTC switch). While the Pharmacy Acts of most provinces "schedule by reference" to NAPRA's National Drug Schedules (NDS), British Colombia, Newfoundland and Labrador and Saskatchewan follow NAPRA's decisions but still maintain provincial approval of scheduling decisions resulting in a waiting period before scheduling decisions can be implemented:

- British Colombia's process establishes a minimum 3 month wait time.
- Newfoundland and Labrador's process establishes a minimum of 1-2 month wait time and;
- Saskatchewan's process establishes a minimum of 6 weeks wait time

Quebec has an independent scheduling process that is slow, unresponsive and lacks transparency. As a result the Quebec scheduling system can't keep up with Canadian switch activity, which mean that Quebecors have restricted access to innovative self-care medicines. Since, 1999, there have been 12 switches that are sold behind the counter in Quebec that are less restricted everywhere else in the country. Although it should be noted that Quebec's Schedule II default policy is a best practice as it automatically adopts Health Canada's switch decision by allotting Schedule II status facilitating market entry. In contrast, the switch remains pursuant to a prescription as a Schedule I drug on National Drug Schedules until such a time when a sponsors files for that decision to be revisited by NAPRA's National Drug Scheduling Committee (NDSAC), which is an unnecessary market restriction. Since Quebec left NAPRA in 1998, NAPRA's NDSAC has made 70 scheduling decisions and Quebec has only made 7 decisions within that same time. The Quebec process is so slow, that Quebecers are waiting on average 3 years, 9 months longer to have the same access to products that are already available in the rest of the country. Overall, in Quebec, there are 68 ingredients where access is more restricted than the rest of the country. As a result, industry is no longer bothering to seek scheduling decision in order provide increased access for Quebecors to innovative consumer health products. In fact, approximately 90% of scheduling decisions are not sought/or successful in Quebec.

International Best Practices

No other country in the world manages conditions of sale of OTC medicines through pharmacy regulatory authorities. We are not the only country to have overlapping federal and provincial

jurisdictions responsible for conditions of sale of OTC medicines. Both the UK and Australia have an overlapping system that impose additional conditions of sale for OTC medicines, requiring some to be sold in a pharmacy environment. However, in both cases, the determination of these conditions of sale in pharmacy environment are ultimately the decision of the federal regulator that is integrated into the Rx-to-OTC switch process. In Australia, as described above, the federal/state/territorial overlap of jurisdiction is managed through a transparent, representative and consultative process managed by the federal regulator. Although there remains the option for states/territories to implement different decisions from the Federal regulator based on local needs, the state must defend how such measures would warrant the additional internal trade barriers it would create. The net effect is that national consensus is the default. In the UK, the conditions of sale are decided by the federal regulator and take effect through national regulation, creating harmonization throughout the country.

Proposed solution

The lack of national harmonization of the conditions of sale for OTC medicines impedes the ability for businesses to coordinate a national product launch, creating significant interprovincial trade barriers for manufacturers and retailers resulting in delays to market access for Canadians. Through the Canadian Free Trade Agreement, the Regulatory Cooperation and Reconciliation Table has committed to address the interprovincial trade barriers caused by drug scheduling that leads to uneven access to OTCs and imposes a high regulatory burden on industry[23]. However, Federal leadership is needed to pull together provincial/territorial support to make this happen. FHCP recommends that Health Canada take over administration of the NDS and integrate drug scheduling into its drug approval process under the *Food and Drugs Act*, which would harmonize the drug schedules themselves. It should be noted that for most provinces and territories this step would be unnecessary as they already reference the NDS. However, for provinces like Quebec with the most differences, a process could be established to reconcile their schedules over time.

5.2 Other barriers limiting innovation and virtual access to self-care products

To support informed selection and use of OTC drugs in a digital environment, electronic tools can be developed to compliment and enhance, not replace the product label and virtual or in-person consultation with health professionals. However, antiquated interpretation of conditions of sale as the "place of sale" and the limited scope of electronic labelling for OTC drugs are barriers to the development of these innovative digital tools to support better informed use in a digital setting.

Health Canada has committed to regulatory modernization to support better- informed consumer health product use. However, they rely on provincial/ territorial pharmacy regulatory authorities to support better informed use beyond the label, through regulation of the conditions of sale. The *Food and Drugs Act* also gives Health Canada the authorities to regulate conditions of sale which could be applied in the digital space that would allow them to build on their existing work on electronic label extensions for OTC drugs.

5.2.1 Need for modernized approach to conditions of sale to accommodate digital access to OTC medicines

Electronic tools like mobile health applications, computer-driven questionnaires, how-to videos,

[23] Regulatory Reconciliation and Cooperation Table Work Plan #2, (2019-2020) https://www.cfta-alec.ca/wp-content/uploads/2019/06/RCT-2019-2020-Workplan-List-of-Measures-Final-May-29-2019.pdf

websites and other media can play an important role to improve self-selection and use. These tools can reduce complexity and emphasize key label information, provide unlimited educational opportunities, and improve health outcomes while mitigating health care costs because of their potential to improve a patient's access to information and care providers[24]. A 2018 panel of consumer behavior experts, health professionals and academics agreed that supported interactions in store and online to collect, disseminate and navigate pertinent information can effectively support safe and effective selection and use[25]. Canadians see value in these tools as well and the role that they could play to increase safe and effective self-care. A recent survey showed that 41% of Canadians agree that if they had the right tools, products, information and services, they would like to diagnose their own ailments and choose their own treatments. Given the opportunity to specify which tools would help assist self-selection, 14% indicated virtual access to health practitioners, 13% indicated access to reliable online information, 10% indicated online diagnosis guides and check lists[26].

Ensuring Canadians have access to online resources and tools is always an important consideration. Internet access, both at home and through mobile devices continues to increase whereby the vast majority of Canadians now have access through multiple formats. In 2018, 91% of Canadians aged 15 and older used the Internet, and 88% of them reported having a smartphone for personal use, and 54% have used their smartphone to purchase products[27]. Canadians are also using their smartphones to manage their health. A 2017 study of Canadians' use of mobile apps and connected smart devices to monitor health and well-being found that 32% of Canadian adults used one or more mobile apps to monitor aspects of their health or well-being in the previous three months. For Canadian adults under 35 years of age in particular, one out of every two people use mobile health apps[28]. It is important to note that the development of these tools are not positioned as an alternative to product labeling or health professional interaction, but rather they can support these interactions to improve understanding and health outcomes. Canadians are increasingly turning online for information and resources to inform the decisions they make about their health and self-care. Regardless of whether consumer health products are ultimately purchased in store or online, the ability for Canadians to access digital decision support tools better aligns with how the path to purchase for these products has evolved, given most health product searches start online. Should access to these consumer health products and services by digital means be interrupted or not be feasible for a particular individual, the usual means of accessing products and in-person health professional consultation through the bricks and mortar domain would always remain.

Legal considerations on conditions of sale

Provincial pharmacy legislation and regulation apply additional conditions of sale to OTC medicines, but the way the provisions are worded, their scope is narrowly describing the place of sale of OTCs in a pharmacy environment, rather than the broader, outcome-based conditions on how they are to be sold. For example, the intent is for Schedule II products is to require intervention by the pharmacist at the point of sale even though a prescription is not required in order to ensure appropriate product

[24]Canada Health Infoway. Mobile health computing between clinicians and patients. White paper. Toronto: The Infoway; 2014 Apr https://www.infoway-inforoute.ca/component/edocman/resources/technical-documents/emerging-technology/1883-mobile-health-computing-between-clinicians-and-patients-white-paper-full-report?lang=en&Itemid=188
[25] Labelling Research Forum https://www.chpcanada.ca/wp-system/uploads/2019/03/LabellingResearchForum_FinalReport-v2.pdf
[26] May 2020 cross-Canada survey of Canadians by Redfern Research focused Canadians' management of their health before and during the COVID-19 pandemic, including their self-care activities and viewpoints
[27] Statistics Canada. *Canadian Internet Use Survey*. https://www150.statcan.gc.ca/n1/daily-quotidien/191029/dq191029a-eng.htm (accessed March 23, 2020).
[28] G. Paré et al. Diffusion of Smart Devices for Health in Canada. Montreal: CEFRIO. 2017.

selection[29]. The provincial legislation and regulation further narrows these conditions of sale to specify that the product must be retained in an area of the pharmacy where is there no public access and no opportunity for self-selection, behind the pharmacy dispensary. This is also the case for Schedule III products where the intent is that the pharmacist is to be available, accessible and approachable to assist patients in appropriate self-selection decisions for these products. Again, the provincial legislation and regulation further limit these conditions in a bricks and mortar retail environment to the "professional services area" directly in front of the dispensary or another area of the pharmacy as long as a pharmacist is available. This narrow regulatory language describing the conditions of sale artificially limits how electronic means can be leveraged to achieve the same intent and outcomes when obtaining consumer health products digitally. For example, electronic tools could be adapted into product websites directing patients to access a virtual pharmacist consultation (via telephone, virtual chat, or video conference) prior to purchase. Integration of digital check lists and decision support tools could support this virtual pharmacist interaction.

International best practices interpreting conditions of sale

In Australia, the conditions of sale are outcome-based (ie. Pharmacist Only and Pharmacy Only) and it is acceptable to meet these objectives through digital means. For pharmacy only medicines, it is acceptable to provide contact information for a pharmacist on the webpage where consumers can view and purchase the product online. When a consumer adds a product to their online cart that requires a pharmacist consultation, the interface requires the completion of self-selection questionnaires prior to purchase. Depending on the answers to the digital self-selection questionnaire, the consumer may be eligible to purchase the product online or be directed to connect with pharmacist through virtual means instead. Alternatively, pharmacist only products would require the consumer to contact a pharmacist, by phone or through virtual chat to approve the online purchase. This flexible approach to interpreting the conditions of sale in a digital environment reduces barriers to product access, without decreasing the risk of inappropriate self-selection.

Legal considerations of e-pharmacy models

Licensing of pharmacies (whether bricks and mortar or an online business) is the jurisdiction of the provincial pharmacy regulatory authorities. The national e-pharmacy model was developed in 2001 and excludes major online-only retailers from selling a significant proportion of OTC products in accordance with their required conditions of sale in a digital environment. We estimate that 39% of marketed OTC DINs are subject to additional restrictions in the retail and online environment, requiring either the intervention or access to a pharmacist at the time of purchase. Approximately 269 marketed OTC DINs that are on Schedule II of the NDS (11% of all OTC marketed DINs) and require a pharmacist intervention prior to be sold and 661 OTC marketed DINS are on Schedule III of the NDS (28% of all marketed OTC DINs) require the availability of a pharmacist at the point of sale. The majority of these were innovative products switched from prescription status and the net result of the NAPRA model is that these OTC products can only be sold by an online retailer that is connected to a bricks and mortar pharmacy.

Under the national model, online-only retailers must invest in a bricks and mortar pharmacy provincially and provide contact information for the pharmacist in charge to meet this standard. It should be noted that the advantage of this model standard is that, unlike the provincial legislation and regulation, it is not overly prescriptive regarding the place of sale in the online environment and provides an outcome-

[29] NAPRA Outline of the Schedules https://napra.ca/sites/default/files/documents/Schedules-Outline.pdf

based means requiring a pharmacist assessment prior to the sale of a Schedule II OTC and requires pharmacist availability and accessibility in order to sell Schedule III products.

The main challenge with NARPA's e-pharmacy model is that it is not adapted throughout Canada and there are additional regulatory barriers imposed provincially that create uneven access to online OTC availability across the country. NAPRA's model is only required in New Brunswick and Manitoba and recommended in Prince Edward Island, while other provinces have additional regulatory barriers to obtaining consumer health products via e-pharmacy, and yet other provinces provide no additional guidance for e-pharmacy (including British Colombia, Nova Scotia, Newfoundland, North West Territories, Yukon, Nunavut). These additional provincial restrictions no longer reflect a recent Federal court decision that have placed limits on the reach of provincial professional regulators into the regulation of e-commerce.[30] Examples of provincial pharmacy legislation that needs to be updated to reflect this new understanding exists in Saskatchewan where pharmacists are not permitted to ship products outside of the provinces if there is reason to believe the products will be shipped outside of Canada where the drug associated with the shipment is promoted by email, internet or any other method accessible outside of the province[31]. Moreover, in Alberta, pharmacists are outright prohibited from selling Schedule II and III products online.[32] These interprovincial differences to e-pharmacy are unnecessary, anti-competitive, create interprovincial trade barriers and uneven access to products and services for Canadians.

Experience with current e-pharmacy models

The current patch work application of an outdated e-pharmacy model is challenging to manufacturers planning national consumer health product launches, to retailers planning national approaches and distribution logistics. Most importantly, from the perspective of the self-care practicing Canadian consumer, it is difficult to understand why certain OTC products can only be purchased in store. It can be frustrating when attempting to purchase OTCs through Canadian online retailers only to find that at the check out that the product cannot be shipped to their location. This frustration is a significant barrier to digital access to self-care treatment options, which can drive Canadian consumers to access the products they are looking for from international black market or grey market products that have not been approved by Health Canada for safety, quality and efficacy.

Domestic best practices addressing federal/provincial overlap regulating retail environments

As e-pharmacy is the jurisdiction of provincial pharmacy regulators, and there exists little motivation to modernize and harmonize at the provincial level. However, there is a role for federal leadership in this space, similar to the approach taken to address the federal/ provincial overlap to the sale of recreational cannabis products. When federal recreational cannabis laws were established, clear authorities governing the sale of cannabis in bricks and mortar retail were attributed to the provinces and territories. The provinces and territories are responsible for establishing, implementing and enforcing their own sale and distribution systems, which may include online sale. However, recognizing that these jurisdictions required more time to implement those frameworks, the Cannabis Act and Regulations created a backdrop legal framework for individuals in provinces and territories without a regulated retail framework to purchase cannabis online from federally-licensed producers[33]. The Cannabis Act

[30] College of Optometrists of Ontario v. Essilor Group Inc., 2019 ONCA 265 https://www.canlii.org/en/on/onca/doc/2019/2019onca265/2019onca265.html
[31] Saskatchewan College of Pharmacy Professionals The Regulatory Bylaws of the Saskatchewan College of Pharmacy Professionals (April 2020) https://scp.in1touch.org/document/3384/Regulatory%20Bylaws_NOV2016.pdf
[32] Alberta College of Pharmacists, Council Meeting Highlights- June 21 2017 https://abpharmacy.ca/articles/council-meeting-highlights-june-21-2017
[33] Department of Justice, Cannabis Legalization and Regulation (2019) https://www.justice.gc.ca/eng/cj-jp/cannabis/

established a class of license to authorize the sale of cannabis products obtained from a licensed producer to adult consumers in Canada obtained online or over the phone with delivery through the mail. This approach created a competitive environment driving each province to develop an online retail model to meet the federal standard. Moreover, a federal mandate for online sale provided clear basis for enforcement nationally.

This same approach to could be taken to enable federal authority for the digital sale of OTC drugs. It would create competition between the digital space, e- pharmacy, and bricks and mortar pharmacies to maximize OTC product availability for Canadians. A clear federal backdrop for online sale of OTCs would also address current gaps in enforcement. Health Canada relies on the provincial/ territorial regulatory authorities to enforce limits on the sale of precursor control substances like pseudoephedrine and ephedrine under the Precursor Control Regulations. However, provincial and territorial pharmacy regulatory authorities generally do not enforce outside of pharmacy and as such, were not monitoring or enforcing against non-compliant online sale of these substances.

Proposed solution

Recommendation 1 b): Lead the modernization of the conditions of sale for over-the-counter creating a federal regulatory backdrop that fully leverages electronic labelling and other digital tools, and enables Canadians access to over-the-counter drugs through digital means in an environment that can be consistent nationally

For example, modernized conditions of sale in a digital environment (in addition to existing bricks and mortar availability) could include the following considerations:

- For Schedule III OTCs (pharmacist availability when OTC products are ordered):
  - The online interface where the OTC product is digitally accessible for sale would be required to include contact information for a pharmacist so the consumer could voluntarily access advice (phone, video call, online chat, corporate 1-800 number, or link to find the nearest pharmacy), OR
  - The online interface where the OTC product is digitally accessible for sale would include the ability for the consumer to voluntarily access a digital self-selection tool
- For schedule II OTCs (assessment of patient need prior to sale):
  - The online interface where the product is digitally accessible for sale would require the consumer to complete a digital self-selection tool. Answering the assessment questions correctly would result in the ability for the consumer to obtain the OTC product. Incorrect answers would direct the consumer to contact a pharmacist via digital means (phone, video call, online chat) and prevent purchase, OR
  - The online interface where the product is digitally accessible for sale would immediately direct the consumer to contact a pharmacist through digital means (phone, video call, online chat) for a consultation about the OTC product use and approve the purchase digitally, as appropriate

5.2.2 Policy barriers limiting scope of electronic label extensions

Self-care products can be safely and effectively selected and used, without the intervention of health professionals. As a result, there tends to be a reliance on the product label as the most important mechanism to provide information to support appropriate selection and use of these consumer health products. However, Canadian manufacturers are challenged to accommodate the demand for more information on limited label space in two official languages, without introducing costly packaging

reconfigurations. Canadians use multiple sources of information, including electronic tools and search engines, to find information to support safe and effective self-care. A recent global study showed that among millennials, the internet is considered to be the most important source of information for health information and treating minor conditions[34]. Given the increased use of online information as support for OTC product selection and use, there is an opportunity to leverage electronic mechanisms to support better informed choices and make these products more competitive.

Domestic best practices for electronic labelling

In recognition of this increased consumer demand for online information, paired with the challenge to accommodate required information on limited package sizes, Health Canada has begun to accommodate electronic label extensions for self-care products. In its guidance to the Plain Language Labelling Regulations, Health Canada enabled manufacturers to shift less critical product information at the point of selection from the product label to an online location by including a URL on the outer package to direct to the consumer to the complete labeling. This was intended to permit more cost-effective implementation of the Plain Language Labelling regulations and was expected to lead to better, less cluttered product labels for affected products. As the URL contains regulated information, guidance prescribing the technical standards for the format and content of these websites were established to ensure principles for factual information (non-promotional), readability, accessibility, consistency were achieved,[35] [36]. However, the scope of OTC drugs that are eligible to use this approach are limited to the lower-risk OTC drugs like sunscreens, acne medications, medicated skin care products, diaper rash products, antiseptic skin cleansers, athlete's foot treatments, and throat lozenges. Approximately two thirds of the remaining OTCs are unable to leverage this innovative labelling solution to help accommodate the ever-expanding requirements for more product information and to create digital platform to facilitate seamless access to reputable health information and digital support tools to inform safe use.

International regulator best practices for electronic labelling extensions

As outlined in section 4.3 of this report, the US FDA recently released guidance inviting electronic images, interactive displays, websites, mobile applications, not only to provide additional information on the safe use of conventional OTCs, but also to enable safe selection and use of more innovative products that may require more complex directions for use than can be effectively communicated in the limited space available on product packaging. [37] For example, prior to purchase of an OTC, the FDA is proposing that a consumer could be required to complete an electronic decision support tool or watch a video prior to being able to obtain the product.

Legal considerations

The legislative definition of a label includes "any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package." Although the legislative definition of a label does not explicitly include the mention of a website, the addition of a URL on the physical outer label was interpreted as content "accompanying" a drug label and thus deemed a part of

[34] Sanofi, Self Care Be your best. Empowering the Net Generation to make the most of self-care (2019) https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/common/docs/about-us/UPDATED-FINAL_Be-Your-Best-Report-2019_03-JULY.pdf
[35] Electronic Canadian Drug Facts Table Technical standards (September 2018) https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-electronic-canadian-drug-fact-table-technical-standards/guidance-document.html#a1
[36] Example of eCDFT format: https://www.coppertone.ca/en/info/general-protection-sunscreen-lotion-spf-60/ ,
[37] FDA, Innovative Approaches for Nonprescription Drug Products (July 2018) https://www.fda.gov/media/114328/download

the product label. This interpretation of the existing legislation provided the necessary flexibility to embrace electronic labels as a solution to accommodate required information in a relevant medium for consumers that is cost effective for manufacturers. Such an approach could also be taken to capture digital support tools within the definition of a label, including online self-selection questionnaires that could be required as a condition of sale. This would allow regulators to fully leverage electronic information and provide Canadian consumers the information and digital tools they need in one electronic location to inform product use.

International Industry Best Practices for electronic label extensions

SmartLabel is a manufacturer and retailer initiative designed to help meet consumer demand for easy access more information about the products that they are looking for that could ever fit on a product label. The initiative was developed in 2016 in the US by the Trading Partner Alliance, the Grocery Manufacturer Association, the Food Marketing Institute and Consumer Goods Forum to provide an online platform for consumers to access detailed, accurate and up to date information about the products they buy. The platform extends beyond regulated label information providing consumers information about how the product is produced and where ingredients are sourced from as well as additional information on third-party certifications and social compliance programs. Now, information is available for over 80,000 products in the US and the platform that can be used as a means to provide digital disclosure where it is acceptable to provide alternatives to on-pack labelling of certain consumer product regulatory initiatives. FHCP is the licensor of the SmartLabel brand in Canada and we will work members on this voluntary industry initiative, and with regulators, to encourage the adoption of regulations and policies that fully leverage the capabilities of e-labelling. As Health Canada developed technical standards for electronic label extensions for certain lower-risk OTC drugs, these standards accommodated the format already developed and in use through the voluntary SmartLabel program.

Proposed solution

As international regulators around the world innovate new regulatory approaches to integrate electronic tools as a means to supplement or extend labels, we need to ensure the Canadian requirements are flexible enough to extend these benefits to Canadians. Canada is in a unique position as a global leader and early adopter of electronic label extensions for OTCs, but other jurisdictions are recognizing digitalization as an opportunity that goes beyond merely reproducing traditional label information. For example, electronic label extensions could be the digital platform for consumers to seamlessly sophisticated digital decision-making tools supporting better informed use.

Recommendation 1 b) Lead the modernization of the conditions of sale for over-the-counter drugs by creating a federal regulatory backdrop that <u>fully leverages electronic labelling and other digital tools</u> and enables Canadians access to over-the-counter drugs through digital means in an environment that can be consistent nationally

5.3 Measures in other jurisdictions to encourage innovation, increase choice and enable virtual access to self-care products

The US FDA is leading policy development on how to incorporate innovative digital technologies as conditions of use to support safe self-selection of OTCs. In 2012, the FDA began consulting on a new paradigm where the agency would approve Rx-to-OTC switches with certain conditions of safe use,

including digital tools designed to assist with self-selection.[38] This policy for this proposed paradigm acknowledges that the under treatment of many common diseases like high cholesterol, high blood pressure, migraines and asthma are a serious public health problem. The objective of the policy is to increase access to treatments for these conditions through Rx-to-OTC switch to eliminate barriers to obtaining prescriptions, decrease costs for consumers, the health care system and improve health outcomes. As switches become more complex, it becomes more challenging to communicate the necessary information to help inform safe self-selection on limited physical label space. This is why, the FDA published a draft guidance in 2018 that invites companies to develop additional labelling content and conditions of use to support self-selection through digital tools.[39] This guidance proposes the use of electronic images, interactive displays, websites, mobile applications not only to provide additional information on the safe use of OTCs, but to be a required condition to support safe selection and use. [40] For example, prior to purchase of an OTC, the FDA is proposing that a consumer could be required to complete an electronic decision support tool or watch a video prior to being able to obtain the product. Such a model would support access to new self-care options easily through digital platforms.

This proactive policy welcoming these innovative approaches has been successful as these tools are currently in development for the US market by a number of FHCP members. Moreover, these digital support tools are exceeding self-selection scores and have the potential to contribute to better health outcomes for products supported and accessed through digital means, rather than a typical bricks and mortar path to purchase[41]. Self-selection algorithms transform label directions into simple questions, chunking information for patients to focus on one question at time. As they answer the questions, the algorithm provides only the questions relevant to their health situation, and they are provided with links to supplementary information to help inform their answers. This enables a personalized labelling approach, cutting down on "information overload" and can highlight the most important health warnings or directions for an individual to maximize health outcomes. These digital self-selection support tools would provide credible information at the right time, when Canadians are researching product options online. They have the potential to improve on how we support self-selection in a bricks and mortar environment by providing supported interactions for a significant proportion of consumers. These tools are not about taking pharmacists out of self-care, but rather repositioning their contributions to facilitate better, simplified self-care consultations and increasing their availability and accessibility so that they can advance new scope of practice.

International best practices

The FDA is inviting sponsor submissions on a case-by-case basis proposing digital tools supporting Rx-to-OTC switch, drawing from existing legal authority to determine conditions of use within section 503(b)(1)(A) of the Food Drug and Cosmetic Act (21 U.S.C. 353 (b)(1)(A)) to establish "collateral measures necessary" to ensure safe use as a non-prescription drugs.

It should be noted these digital tools - like the labels themselves- are developed through a series of proprietary, iterative consumer and clinical studies to demonstrate efficacy, which require a significant time and resource investment. Additional studies to validate the electronic tool and test their functionality could be required beyond the suite of iterative consumer studies usually employed demonstrate safe selection and use in a self-care environment. Although we have not yet seen an Rx-to-

[38] Department of Health and Human Services, FDA. Notice of Public Hearing: Using innovative technologies and other conditions of safe use to expand which drug products can be considered non-prescription, Self-Care Journal, (2012) https://selfcarejournal.com/wp-content/uploads/2015/09/FDA-notice-34.69-74.pdf
[39] FDA, Innovative Approaches for Nonprescription Drug Products Guidance for Industry (2018) https://www.fda.gov/media/114328/download
[40] FDA, Innovative Approaches for Nonprescription Drug Products (July 2018) https://www.fda.gov/media/114328/download
[41] Julie Aker, Concentrics Research https://www.pharmdevgroup.com/wp-content/uploads/2014/01/March-23-2012-Day2.pdf

OTC switch in the US supported by these digital tools, a sponsor could be eligible for data protection. In the US, Section 505 [21 U.S.C 355] (c)(3)(F) of the Hatch/Waxman Act[42] establishes a period of 3-year of data protection for existing active ingredients that have been approved under another application if the application contains results of new clinical investigations essential to the approval of the application. These additional 3 years have been a major driver of the Rx-to-OTC switch process in the United States, by providing an incentive for manufacturers to conduct research on potential consumer uses for established prescription drugs. New clinical investigations to support new digital support tools could also be eligible for these protections, including studies to support Rx-to-OTC switch. It should be noted that the EU also offers one year of data protection for new clinical data to support new claims on existing products, similarly driving switch in those jurisdictions.

Canada does not offer any data protection for proprietary clinical data to support regulatory approval of a switched product, which is why Canada lags behind its main trading partners by seven to ten years in Rx-to-OTC switch activity. The innovative company will have to spend three to four years and tens of millions of dollars to gain market access, but will generally find themselves facing second-entrant competition (approved largely on the basis of the innovator's product submission and data) on store shelves within a few months of the innovative product's launch. This drastically reduces the chances of the innovative product's success in the marketplace, as the time to profitability of such products is usually measured in years.

It should be noted that regulatory incentives are not the only way to reward and encourage innovation. Within this context, with the federal integration of conditions of sale and the establishment of a federal backdrop for online access to OTC drugs, Health Canada could reward innovation by offering more favorable online conditions of sale. For example, if a sponsor invests in a digital support tool that would intervene and prevent purchase if the algorithm questions were not answered correctly, then Health Canada could establish conditions of sale for this product to be sold online as long as it accompanies this tool. Other sponsors of similar products would not be eligible to sell the product online without a comparable decision support tool. As a result, the competitor product could continue to be sold behind the counter in a bricks and mortar pharmacy or in accordance with provincial e-pharmacy models that would require digital pharmacist intervention prior to sale.

Proposed solution

Health Canada is currently consulting on OTC regulatory reform through the Self-Care Framework. Through this initiative we have the opportunity to establish regulatory incentives for innovation, similar to the US FDA to encourage the development of digital support tools.

Recommendation 1 c): The Competition Bureau should advocate that Health Canada introduce regulatory incentives to encourage industry to develop innovative tools to support informed selection and access to all over-the-counter drugs through digital means

5.4 Policy barriers to limiting health information sharing

[42] "Hatch- Waxman Act" 98th Congress (1983-1984) https://www.congress.gov/bill/98th-congress/senate-bill/01538

The free flow of personal health information is a fundamental requirement to elevate the utility of digital health tools so that they can achieve their full potential to support informed digital self-selection and use. Imagine if a digital health tool to design to support informed selection and use could tap in to existing medial health records, test results and support digital interaction with health professionals. This will be able to provide real-time health assessments and feedback to Consumers as they manage minor ailments and chronic diseases remotely through supported self-care.

The first step in this interconnectivity is the ability for Canadians to access their Electronic Health Record (EMR). Electronic health record data is now available for 93.8% of Canadians[43], however, as of 2018, only 22% of Canadians are able to access them[44]. Some health care organizations, such as hospitals, may have developed or endorse digital tools and applications for use in their clinical environments that may link directly to an EMR, patient portal, or government data repository. Interconnectivity of a medical health records can facilitate better clinical care, decision making while helping Canadian manage their health with much more autonomy by engaging health care professionals when they really need them. Those that are able to access their EMRs report that they are better able to manage their health and work in partnership with their care providers, which has saved unnecessary in person visits and phone calls.

Legal considerations

As with any data sharing activity, the benefits of accessing this information must be balanced with mitigating the potential risk risks to privacy. Canada's private sector policy law- the Personal Information Protection Electronic Documents Act (PIPEDA) provides a balance between commercial interests and consumer protection through a nationally consistent mechanism to achieve definitive consent. While the private sector has adapted to these requirements, the public sector has been slow to adapt consent-based policies to enable Canadians to access their own EMR across the country so that the data can be used by third party app or website in a certain way.

Best Practices

The Canadian Medical Association outlines how physicians may wish to recommend the use of mobile health applications, which contribute to robust existing data repositories, while respecting patient privacy. The CMA outlines that physicians may wish to enter into and document a consent discussion with their patient, which can include the electronic management of health information or information from electronic management platforms like mobile health applications. This agreement may include a one-time conveyance of information and recommendations to cover the elements common to many mobile health applications, such as the general risk to privacy associated with storing health information on a mobile device, that could be conducted in accordance with a national privacy protection framework.[45] Policies to encourage public health authorities to enable patient access to their own, reputable, accurate heath data in portable, adaptable formats could further improve health outcomes and facilitate efficient and informed interconnectivity of self-care and health professional care.

Proposed solution

[43] Canada Health Infoway, Progress in Canada (2020) https://www.infoway-inforoute.ca/en/what-we-do/progress-in-canada
[44] Canada Health Infoway, Connecting Patients for Better Health (2018) https://www.infoway-inforoute.ca/en/component/edocman/3564-connecting-patients-for-better-health-2018/view-document?Itemid=101
[45] CMA Guiding Principles for Physicians recommending mobile health applications to patients 2015) https://policybase.cma.ca/documents/PolicyPDF/PD15-13.pdf

Recommendation 1 d): The Competition Bureau should advocate that Health Canada establish policies to encourage digital health information sharing between institutions and with third parties, within a consistent national privacy protection framework to boost innovation in digital health

5.5 Lack of an economic mandate as a barrier to innovation and choice of self-care products

Improving regulator's understanding of the economic impact of regulations is partly a cultural issue. Very few regulators have experience in the industries they regulate, so this understanding has to be gained on the job. Refining the role of the regulator to engage early, and more often with the industries they regulate can be made possible by shifting their regulatory mandates to make economic growth and regulatory efficiency a priority.

In the Fall 2018 Economic Statement[46] the Canadian government committed to integrate economic growth as a integral part of regulator's mandates, while still maintaining a regulatory system that protects first and foremost the health and safety of Canadians. An economic mandate would encourage departments to better address economic considerations when designing and implementing regulations to ensure our regulatory system is evergreen, nimble and effective. A high level mandate needs to be supported by tangible tools to guide regulators about how to execute new roles for regulatory and economic efficacies as the culture within the organizations evolves overtime to gain a stronger understanding of the sectors they regulate. As a start, we recommend adoption of the recently published Competition Assessment Tool kit[47] by each regulator and that it should be formally integrated into regulatory policy via the Treasury Board Cabinet Directive on Regulation.[48]

The Competition Assessment Tool kit should used to consider the impact of a regulatory or policy measure on digital access to self-care products. In a consumer-centric market, advances in e-commerce is a disruptive force in the Canadian consumer health product industry that will drive changes to consumer self-care behavior and could make it difficult for Canadian businesses to compete. We need to ensure that future regulatory proposals are designed with the potential impact of e-commerce in mind and how it can be used to circumvent Canadian regulatory barriers. For example, Canadians can access cheaper products from foreign jurisdictions online that have not been subject to the same regulatory controls as Canadian products to ensure safety, quality and efficacy. Introducing added regulatory compliance costs to Canadian businesses makes it more difficult to compete with foreign businesses selling to Canadians, potentially resulting in increased risks to health. Canadians seeking the lowest possible price for their products, go around Canadian regulatory barriers by purchasing products that do not need to comply. Also, Canadians are going to seek out the most convenient way to obtain the self-care products they need to get relief of their minor ailments. With same day, free shipping, Canadians could obtain products faster digitally. Regulatory requirements need to be developed in a way that enables this path to market rather than unnecessarily restricting it. Novel mechanisms like videos, digital decision support tools, the online availability or interaction with pharmacists through video calls or chats could be leveraged in these instance to accommodate, and not hinder, digital realities.

International best practices

[46] Government of Canada, Fall Economic Statement 2018, Chapter 3-Confidennce in Canada's Economic Future https://www.budget.gc.ca/fes-eea/2018/docs/statement-enonce/chap03-en.html?wbdisable=true
[47] Competition Bureau, A Step-by-step guide to Competition Assessment, August 2020 https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04546.html
[48] Treasury Board Secretariat of Canada, Cabinet Directive on Regulation, 2018 https://www.canada.ca/en/treasury-board-secretariat/services/federal-regulatory-management/guidelines-tools/cabinet-directive-regulation.html

US FDA's economic mandate reinforces the impact of innovation on public health. The FDA is responsible for "advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."[49] The European Medicines Agency is also committed to enabling timely patient access to new medicines and plays a vital role in supporting medicine development for the benefit of patients. Specifically, they play a role in supporting research and innovation in the pharmaceutical sector, and promotes innovation and development of new medicines by small and medium sized European companies[50].

Flowing from these mandates, has grown a culture of supporting innovation and growth that has been anchored by regulatory data protection as discussed under section 4.3 of this report. Under this approach, second entrants are not allowed to leverage the innovator's data for a period of time, ranging from one to five years depending on the jurisdiction, after the approval of the innovative product. There are no direct authorities under Canada's *Food and Drugs Act* permitting regulatory data protection to be applied for economic reasons. Health Canada officials tell us that regulatory data protection can only be enacted in response to an international trade agreement or through conditional licensing, which imposes additional regulatory burdens on the innovator. This severely limits Health Canada's ability to regulate efficiently and the Canadian industry's ability to innovate and grow. Relying on trade policy to address regulatory inefficiency and its distortion of market dynamics is neither proactive nor effective. The ability to address the marketplace distortions created by regulation directly, through measures such as regulatory data protection, would require new authorities under the *Food and Drugs Act* and would allow the Canadian industry to enter a much stronger period of innovation and growth, without affecting the primary function of the *Food and Drugs Act* to protect the health and safety of Canadians.

Proposed solution

Recommendation 2) The Competition Bureau should advocate that the Treasury Board advance the development of economic mandate within all federal regulators and require a competition assessment when developing policies and regulations

6.0 Summary of Recommendations to improve virtual access to self-care products

The modernization of legislation, regulation and policies governing access to self-care products can further support the development of digital solutions to give Canadians access to innovative, necessary self-care products and services. Establishing policies to enable greater digital access to self-care products and health professional self-care services, while at the same time ensuring safe self-selection, is evermore important due to pandemic public health strategies that restrict movement and encourage the public to practice self-care.

Recommendations:

1) **The Competition Bureau should advocate that Health Canada:**
   a) **Lead the federal integration of nationally harmonized provincial drug schedules into the regulatory renewal initiative for over-the-counter drugs known as the Self-Care Framework;**

[49] FDA What we do https://www.fda.gov/about-fda/what-we-do#:~:text=Freedom%20of%20Information-,FDA%20Mission,and%20products%20that%20emit%20radiation.
[50] EMA, What we do https://www.ema.europa.eu/en/about-us/what-we-do#:~:text=The%20mission%20of%20the%20European,the%20European%20Union%20(EU).

b) Lead the modernization of the conditions of sale for over-the-counter drugs creating a federal regulatory backdrop that fully leverages electronic labelling and other digital tools, and enables Canadians access to over-the-counter drugs through digital means in an environment that can be consistent nationally;

c) Introduce regulatory incentives to encourage industry to develop innovative tools to support informed selection and access to all over-the-counter drugs through digital means;

d) Establish policies to encourage digital health information sharing between institutions and with third parties, within a consistent national privacy protection framework to boost innovation in digital health;

2) The Competition Bureau should advocate that the Treasury Board advance the development of economic mandates for all federal regulators and require a competition assessment when developing policies and regulations.