North American Trends in the Consumer Health Product Industry

Submitted to the Regulatory Cooperation Council

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Executive Summary

Consumer Health Products Canada (CHP Canada) and the Consumer Healthcare Products Association (CHPA) respectfully submit this brief to Health Canada and the United States Food and Drug Administration (U.S. FDA) senior officials. It includes strategic and technical level input as the organizations consider the short- and medium-term activities under the Regulatory Cooperation Council (RCC).

Overall, the consumer health product industry has seen incredible growth and change over the past 10 years, driven by globalization, new technologies and consumer demands for increased choice. In order to keep pace with this force, regulators will need to ensure regulatory frameworks and policies are aligned, can adapt, and encourage innovation instead of create barriers for businesses.

To this end, CHP Canada and CHPA have identified recommendations and opportunities for regulatory alignment for consideration, within the scope of the Regulatory Cooperation Council's work:

Long term Objectives:
- Health Canada and the U.S. FDA continue to collaborate through existing multi-lateral forums
- Health Canada and the U.S. FDA institutionalize Regulatory Cooperation

Medium term Objectives:
- Canada integrates regulatory cooperation into the process for developing regulations
- Health Canada establishes a policy to enable the Canadian industry to attest to U.S. OTC monographs.
- Canada and the U.S. ratify the Trans-Pacific Partnership
- Health Canada and the U.S. FDA strengthen mutual reliance on drug good manufacturing practices (GMPs)

Short term Objectives:
- Health Canada adopts regulatory provisions for data protection for non-prescription drugs
- Health Canada and the U.S. FDA achieve commitments from existing RCC work plans
- Health Canada and U.S. FDA incorporate new initiatives into RCC work plans to address the medium and longer term goals.

CHPA and CHP Canada appreciate the opportunity to provide feedback and look forward to working with the Office of Information and Regulatory Affairs (OIRA), the Privy Council and the Technical Working Groups to support implementation of our suggestions.
Purpose

The purpose of this brief is to respond to the Request for Stakeholder Submissions that was sent by the Regulatory Cooperation Council Secretariat on January 29th 2016. The request sought input from stakeholders for two purposes (1) to provide information on industry trends for consideration by the senior officials at their binational meeting that will be held on May 4th 2016 and (2) to provide input into the Technical Working Group meetings that will follow as they develop their 2016-2017 work plans.
Who we are

**Consumer Health Products Canada**

CHP Canada is the national industry association that represents the companies that make evidence-based over-the-counter medicines and natural health products. These are the products you can find in medicine cabinets in every Canadian home. From sunscreens and vitamins to pain relievers and allergy medications, people use consumer health products to maintain their health and manage their minor ailments. The $5.6 billion dollar per year consumer health product industry represents about 50,000 over-the-counter and 20,000 natural health products and employs approximately 56,000 Canadians. CHP Canada is committed to working with our members, the broader health care sector, and governments for the growth of the evidence-based consumer health products market.

**Consumer Healthcare Products Association**

The Consumer Healthcare Products Association (CHPA) is the 135-year old trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system $6-$7, contributing a total of $102 billion in savings each year. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

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Emerging trends in the consumer health product industry

How the sector has evolved in the past 10 years

Canadian context

The Canadian industry has grown steadily in the past 10 years due to two main drivers (1) innovation and switch and (2) growth through enhanced trade.

Growth by innovation and switch in Canada

The main driver for growth in the consumer health product industry is when prescription drugs are switched to non-prescription status, creating new options for Canadians to practice self-care. To satisfy the regulatory requirements for switching prescription products, new clinical data is required to demonstrate the product can be used safely and effectively without the intervention of a prescriber. Unlike the U.S., Canada does not offer any data protection for the proprietary clinical data to support regulatory approval of the switch product. The Hatch-Waxman Act, introduced in 1984, provides a three-year market exclusivity period for OTC submissions supported by proprietary requiring clinical trials, which includes new indications for existing products. This provision has been a major driver of the prescription-to-OTC (Rx-to-OTC) switch process in the U.S., by providing an incentive to conduct research on potential consumer uses for established drugs. These regulatory and policy incentives provided in the U.S. and the UK respectively have resulted in Canada lagging behind in switch. For example, after a new switched product is introduced into the U.S., Canadians wait an average of seven years until it is introduced in Canada. Generally, Canada is one of the top 10 OTC markets in the world, however, when global multi-national companies are prioritizing the countries in which to launch innovative switch products, Canada doesn’t make the cut due to its lack of regulatory and policy incentives that support innovation.

However, switch activity in Canada has increased dramatically in the past few years as a result of Health Canada's measures in 2013 to make the Rx-to-OTC switch process faster and more efficient. There have been 13 switches in the past two years – the same number of switches observed in the previous 13 years in Canada. Canada's lag in Rx-to-OTC switch has resulted in an industry with enormous growth potential. Moreover, the adoption of regulatory and policy incentives similar to the U.S. and UK are expected to have a similar impact on industry growth and switch in the future.

Growth through enhanced trade

Over the last decade, consumer health product exports have almost doubled (93%), more than three times the growth of Canada’s total exports over the same period (27%)². This growth was led

by natural health products (NHPs) and is largely attributed to the effect of a modernized regulatory regime for these products. Modernization of the regulatory regime for OTCs would similarly support stronger trade growth in that sector.

U.S. Context

In the past 10 years, the U.S. OTC industry has grown over 160% and is estimated to generate $40 billion in sales. The top five categories that contribute about 72% of total OTC sales are respiratory ($7.7 billion), oral care ($4.2 billion), gastrointestinal ($4.2 billion), internal analgesics ($3.8 billion) and eye care ($1.7 billion). The key growth categories for OTCs in 2015 were respiratory (+10%), hair growth (+7.4%), external analgesics (+6.8%) and feminine needs (+6.6%).

Over the last few decades, the variety of OTC medicines available to consumers has expanded significantly and this growth is historically driven by Rx-to-OTC switch. In fact, more than 700 OTC products on the market today use ingredients or dosages that were once available only by prescription. In 2015, Rx-to-OTC switch accounted for 19% of OTC sales and 27% of growth.

For nearly 40 years, consumers, and the healthcare system, have benefitted from Rx-to-OTC switches. This track record suggests there is continued promise for Rx-to-OTC switches in the future. We can expect the role of OTCs medicines to expand even further as the FDA considers a new Rx-to-OTC paradigm that would expand availability of certain OTCs.

New technological advances that may influence the sector and regulatory system

Canadian context

New technological advances for consumer health products are primarily driven by consumer demand for (1) more safe and effective self-care options through switch and (2) incremental improvements and modifications to existing products.

Advances from new switch products

Rx-to-OTC switches have evolved over decades, as have the types of evidence and studies to

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support them. In the past, prescription medications became switch candidates if it treated a condition that was easily recognized and had a high margin of safety. Switches have moved beyond the common idea that OTCs are for self-diagnosed symptoms, or for a limited duration of use, or could require initial diagnosis by a doctor. Examples like Nicotine replacement therapy and Orlistat to aid in weight loss have indefinite durations of use. Figure 1 depicts a graphic that maps potential self-care indications according to conditions that are short term vs. long term use and conditions that are suitable for self-diagnosis vs. conditions that require prior consultation and diagnosis by a health care practitioner.

Figure 1: Conditions mapped according to self-care potential and chronicity

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Indications that are currently suitable for self-care are in the top half of the chart in Figure 1, and future indications for considerations are located in the bottom half of the chart. In Canada, federal and provincial governments to ensure regulatory frameworks can enable a collaborative care setting to adapt to this increasing consumer demand for access to innovative, and progressive switch options for self-care.

**Incremental advances to existing products**

The consumer health products industry is very sensitive and responsive to consumer demands. Companies perform market research to identify new consumer needs, niche markets and identify improvements to existing products. Improvements can include new packaging, delivery systems, new combinations of existing ingredients and novel uses for existing products.

**Innovative packaging**

Examples of innovative packaging include new forms of child resistant packaging, new dosing devices (i.e. oral syringes, dosing cups) or flow restricting devices to help mitigate accidental ingestion. As regulators demand more information on product labels, the industry is turning to intelligent packaging solutions that can interact with smart phones and detect whether a package has been opened.

**Innovative delivery systems:**

Examples of innovative delivery systems include sustained release dosage forms, tamper resistant dosage forms, transdermal patches, oral thin films, or gums. Sustained release dosage forms are designed to release a drug at a predetermined rate by maintaining a constant drug level for a specific time period. This enables consumers to take product less frequently but with more consistent health outcomes over time. Tamper-resistant dosage forms are designed to prevent product abuse and misuse. Lastly, alternatives to oral tablets are driven by consumer demand to make medications easier to administer to children.

The industry also innovates by identifying novel combinations of existing ingredients or finding new uses for existing ingredients. For example, for heartburn sufferers, Pepsid Complete™ combined calcium carbonate as a fast acting antacid to neutralize stomach acid with famotidine, a long lasting acid reducer which addresses two needs in one product.

All of these incremental advancements create challenges for regulators to ensure regulatory frameworks can adapt and encourage these new technologies in a harmonized approach, instead of stifling innovation and opportunity.

**U.S. Context**

There is a long history of switches in the U.S., breaking what was thought to be the standard paradigm for OTC medicines. Switches have leveraged new studies and tools such as help lines or on-line, personalized information to support optimal outcomes, including behavior modification. These evolutionary changes in the industry were achieved over decades and benefitted consumers and the healthcare system.

In 2012, the FDA took strides to address this trend by undertaking the Nonprescription Safe-Use Regulatory Expansion (NSURE) Initiative. It addresses the undertreatment of common disease or conditions (like high cholesterol, high blood pressure, migraines, headaches or asthma) by allowing
prescription drug products to be available without a prescription under new conditions of safe use. These conditions may be specific to a drug product and may include interactions with healthcare providers or new technologies to aid in the self-selection and safe use of the product. Pharmacist intervention to confirm a diagnosis, or testing or routine follow up could also be a condition of safe use. Application of technologies on a case-by-case basis, supported by data, can provide a means to achieve novel, future switches in exceptional cases where reliance on the Drug Facts label alone might be insufficient to assure proper product selection and use by consumers.

**New technologies**

A significant number of technologies have been developed and are in use in today’s marketplace in a variety of industries. These technologies could be easily reapplied to the OTC setting. Examples include:

- An expansion of the current Drug Facts label to include video or audio (talking) technology, online or in store questionnaires;
- 2D bar codes that can be scanned with a smart phone or with an in store scanner to allow access to more information about the product;
- In store diagnostic testing such as blood pressure or glucose measurement;
- In store educational material at shelf or via an informational kiosk;
- Kiosks that can administer a questionnaire, read data on a smart card, or control access to the product;
- Age, gender, or subpopulation restrictions controlled at check-out via scanning technology.

Portable electronic medical records are another means to support safe use of medicines.

In the future, innovative switches should be made possible by a regulatory framework that accommodates greater use of tools and technologies. Looking ahead, if some future Rx-to-OTC switches require fresh interpretations of existing policies on authority or enforceability, to finding an appropriate legal and regulatory path to market.

Technology has also created new platforms for consumers to know more and to have access to more health information than ever before. There are now more cell or mobile phones and tablets than there are people in the U.S. Consumers can now access a wealth of information at home or almost anywhere, to learn about a disease or condition, or seek information about conditions and potential treatments. Google estimates the number of platforms or sources consumers use to make product decisions doubled over the past year. And this explosion includes healthcare and OTCs. For instance, Google estimates search queries for cold and flu medicines more than doubled from 2009 to 2012. Pain management queries increased 110% over that same time period. Our collective challenge is to keep up with consumer capabilities and demands for product information.

**Changes in manufacturing/ supply chains and their impact on the regulatory system**

**Canadian context**

Globalization has enabled the consumer health product industry to obtain global economies of scale and has impacted how and where companies choose to source ingredients and manufacture products.
Foreign sites

Most Canadian products include active pharmaceutical ingredients (APIs) and non-medicinal ingredients that have been sourced internationally. It is estimated that India and China currently supply 40% of APIs used in the U.S., which will double to 80% in the next 10 years. Health Canada's own data of API activities in Canada show the same trend where 61% of Canadian establishments are importers of APIs, and approximately 15% of API foreign sites are located each in emerging markets like India and China.

The quality of ingredients and products coming from foreign sites is a mutual priority of the industry and its regulators. The consumer health product industry goes to great lengths to establish robust quality agreements and validate suppliers to ensure products are compliant. Regulators should recognize how relationships and agreements with foreign suppliers are established and partner with domestic regulated companies to maintain compliance at foreign sites throughout all stages of the supply chain. Given limited inspection resources available to regulators and continued pressure to lower costs and improve productivity and efficiency, there are opportunities for regulators to rely on each other's inspection resources and reattribute resources to focus on higher risk foreign sites of mutual interest.

Manufacturing

With the continued trend towards mergers and consolidations within the consumer health products industry, companies are seeking better global alignment with their manufacturing processes. For example, it is not uncommon for a multi-national company to perform global manufacturing for a consumer health product in one location and packaging and labelling in another. This requires moving products across borders in various stages of the development process, even if the products are not destined for that country. Regulators need to ensure existing guidance and policies to protect against product diversion are updated to recognize how finished products now flow through the global supply chain.

For companies who choose to outsource manufacturing activities, often contracts are coordinated globally for a product type like a particular OTC brand. For example, packaging contracts are often coordinated internationally for the North American market. As a result, regulatory decisions that impact packaging configurations unique to the Canadian environment are difficult to coordinate, and costly and it may be difficult to justify to continue to market the product in Canada. Regulators need a better appreciation for how globalization shapes how packaging and labelling decisions are made and how country-specific requirements can create significant barriers for business.

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8 Nayeri, G., Implementation of Canadian Regulatory Framework for APIs, HPFBI Stakeholder Presentation, March 12 2015
**U.S. Context**

In the 2011 Special Report: Pathway to Global Product Safety and Quality\(^9\), the FDA outlined their vision for the next decade recognizing that product safety and quality no longer begin or end at the border. In response to increasing globalization, FDA has shifted its focus on inspections at domestic production facilities and ports of entry to have a more international reach.

FDA expanded its capabilities and regulatory authority to better identify and target high-risk products before they enter the country and has collaborated with its counterparts in Australia on drug inspections. It also engaged in international consortiums to increase harmonization via the International Conference on Harmonization (ICH) and the Pharmaceutical Inspection Convention/Pharmaceutical Cooperation Scheme (PIC/S). Despite these efforts, the FDA admitted in the report that "FDA does not -nor will it- have the resources to adequately keep pace with the pressures of globalization." It is not feasible for the U.S. FDA to inspect every high-priority international pharmaceutical facility. The report also indicated that FDA can no longer rely on the historical tools, activities, and strategies to regulate products and that it will face a transformation in the next decade to be a truly global agency. A key part of this transformation is to partner closely with foreign regulators to share information, effectively allocate resources based on risk, and leverage efforts of other government coalition members, industry and third parties.

The Regulatory Cooperation Council's mandate provides the ideal framework for the FDA to collaborate with Health Canada to achieve part of their long term vision for the future, particularly by increasing mutual reliance on each other's inspection resources with respect to drug GMPs.

**Consumer perspectives and preferences**

**Canadian context**

Canadians have been taking on a bigger role in their own health care. This is particularly evident in the area of self-care where Canadians are making more decisions about how to improve and maintain their health with the use of products that they can chose and use on their own.

Canada has a strong culture of self-care. A recent study shows three quarters of Canadians are confident about treating their minor ailments themselves. When faced with a minor ailment, 59% use an OTC medicine to help them get relief.\(^{10}\) CHP Canada's 2010 survey shows that 42% of Canadians take consumer health products every day and 31% of Canadians use products a few times each week, or every few weeks\(^{11}\). Of those who practice self-care, 41% actively seek out new


\(^{11}\) Redfern, M., Consumer Views of Safety and Efficacy Issues Related to Consumer Health Products and Natural Health Products (2010).
OTC medications to get relief from their minor ailments on their own. This consumer driven demand for new safe and effective products will put pressure on regulatory systems to encourage innovation and enable greater access to new self-care options.

Self-care can be done independently or in collaboration with health professionals, the latter imposes a significant demand on limited healthcare resources (Figure 2). We estimated that one in seven Canadians with minor ailments visits a doctor as a part of a collaborative approach to self-care. However, doctor consultations for three common minor ailments are estimated to cost the healthcare system almost a billion dollars annually. CHP Canada has shown that if only 16% of minor ailment sufferers, who said their symptoms were mild, practiced self-care instead, it would free up enough physician time for 500,000 Canadians to gain access to a family physician who currently are without one. Given the cost-savings potential of self-care, federal regulators will be challenged to work collaboratively with provincial and territorial counterparts to recognize the direct and indirect benefits of self-care as an economic driver and a critical part of the healthcare system delivery.

Figure 2: Impact of self-care on the Canadian healthcare system

Comparing Canadian and American self-care behavior, a 2002 study showed that compared with Americans, Canadians frequently use OTCs to treat minor ailments and are twice as likely to consult
a pharmacist (38% vs. 20%) and half as likely to consult a doctor about OTCs (21% vs. 44%)\(^\text{12}\). This may be due to differences in healthcare systems and how conditions of sale for OTCs are regulated in Canada may contribute to these differences. In brief, the Canadian federal government determines the conditions of sale of a drug to be pursuant to a prescription or not (ie. OTC status) and the Provincial governments establish the conditions of sale of drugs within a pharmacy environment. Provincial governments, through the Pharmacy Acts, can determine that an OTC needs to be sold pursuant to prescription from a health care practitioner, or requires pharmacist intervention (these products are located behind the counter in a pharmacy), pharmacist supervision (these products are located in front of the pharmacy counter), or can be sold in any retail outlet. The same frameworks to regulate the conditions of sale of OTCs within a pharmacy environment do not exist in the U.S., which may be a factor contributing to the greater likelihood of Canadians to consult pharmacists for OTCs. Nevertheless, Canadians’ strong relationship with pharmacists can be leveraged by both federal and provincial governments as they collaborate to improve access to affordable medicines. For example, better integrating the Rx-to-OTC switch process with the provincial processes for determining conditions of sale in a pharmacy setting would help to improve access to affordable OTC medicines.

Canadian consumers have access to more health information than ever before, which may be contributing to their desire to take a bigger role in their own health care. A 2015 survey conducted by CHP Canada found that, when faced with a minor ailment, the three most commonly sources of information they consult are the (1) information that came with the product, (2) a friend or family member for advice, and (3) the internet, specifically Google to gain information about how to treat their ailment. Canadian consumers do not generally turn to Health Canada as a source for information about consumer health products. This reality needs to be taken into account by Health Canada as they position themselves to become a global leader in health product transparency. The aims of Health Canada’s Transparency and Openness Framework\(^\text{13}\) are to improve access to timely, useful, and relevant health and safety information to help Canadians make well-informed decisions about their health. Given what we currently know how consumers seek information on health products, collaborating with industry and stakeholder partners will be imperative to achieve the objectives set out in the framework.

\(^{12}\) Harris Interactive. Attitudes and Beliefs about the use of over-the-counter medication: A Dose of Reality. NCPIE 2002 http://www.bemedwise.org/survey/final_survey.pdf

U.S. Context

More and more Americans are taking their health into their own hands, and they are doing this with the help of OTCs. Eighty percent of consumers think this trend is positive for Americans. For the more than 240 million Americans who use OTCs every year, these remedies are a trusted and affordable way to get well, stay well, and feel well.

Recent research captures the importance of OTC medicines to consumers. A 2011 survey, revealed that 89 percent of consumers believe OTC medicines are an important part of their overall family healthcare. A 2013 survey reinforces this statistic, finding that nine out of 10 Americans say that OTCs are an important part of their family healthcare.

Another 2013 study revealed that two-thirds of consumers surveyed prefer to use OTCs instead of a prescription when the OTC is available.

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15 Unlocking America’s Medicine Cabinet, Edelman Berland, February 1, 2013.
OTCs are highly trusted as safe and effective treatments for many health issues. The most important factors in determining consumers’ trust in an OTC are that the medicine will work for them, will be as effective as a prescription, does not have many side effects, and is recommended by their doctor. American consumers are also very knowledgeable about selecting appropriate OTC medicines to treat their own symptoms. Nearly two-thirds of consumers report that they understand what the ingredients in different OTCs do, which leaves both a responsibility and opportunity for industry and regulators to continue to educate the remaining public about OTCs, especially how and why to read and follow the Drug Facts label, which lists active ingredients. When it comes to choosing an OTC, 89 percent of consumers choose which OTC to buy based on the symptoms it treats.

The 2013 survey also found that one in four respondents identified themselves as being someone “others often ask for advice on what OTC medicines they should take.” These individuals can be considered “Family Health Influencers.” They are consumers who are more likely to report that they understand what the ingredients in different OTCs do, know what OTCs to take or give to others, avoid going to the doctor unless they absolutely have to, and almost always turn to the Internet to diagnose their symptoms or others’ symptoms.

The availability of OTCs creates significant value for the U.S healthcare system. OTCs generate $102 billion annual value relative to alternatives by savings generated from avoided doctor’s visits and diagnostic testing, and drug cost savings. Just in the case of OTCs used to treat cough, cold and flu, it is estimated that this saves the healthcare system $4.75 billion each year. If OTC medicines were not available, more consumers would seek prescriptions, causing a surge in office visits that would require 56,000 additional full time medical professionals to accommodate. On average, it is estimated that for every dollar spent on OTCs, it saves the U.S. healthcare system $6-7.

In the future, our healthcare system will continue to evolve, and we must advance the ideas that make affordable self-care solutions more accessible today than any point in our history.

**Market place trends that are changing how we do business**

**Canadian context**

The consumer health product market is growing and changing. Twenty years ago, OTCs used to be primarily sold in standalone pharmacy stores. Now, these products are being sold in an increasingly wide range of locations from gas stations, to pharmacies, to health food stores, to supermarkets, to online stores.

In a supermarket setting, more foods are being approved to make health claims (like disease risk reduction claims for high blood pressure, osteoporosis, heart disease, cancer and dental caries) which blurs the lines between drugs and foods. It becomes ever more important for regulators to apply a consistent standard of evidence when approving health claims so no matter what products consumers chose; they can have a reasonable assurance that it will be effective.

In the future, the growth of e-commerce and the use of hand held communication technologies to interact with product labels will enable Canadians to interface with and purchase consumer health products in new ways. It is important that regulatory systems are able to keep pace with this change.

At the same time, the roles of health professionals are being re-examined with a view to ensure each is able to contribute optimally to cost-effective primary health care. As a result, more types of professionals are able to prescribe certain kinds of medications. For example, the pharmacist scope of practice is expanding across Canada such that they are able to prescribe prescription drugs for minor ailments in 8 of the 13 provinces and territories. However, these programs need to ensure optimal therapeutic outcomes are delivered in the most cost-effective manner, in a way that empowers consumers to practice self-care instead of discouraged.
CHP Canada’s 2014 survey showed that pharmacist assessments would be widely used if available and over 90% of people seeking a formal minor ailment consultation from pharmacists would be people who have previously practiced self-care, which would actually increase, not decrease, healthcare system costs.  

Changes in the retail landscape for consumer health products have triggered an evolution in how non-prescription drugs are scheduled, which determines what types of stores they can be sold in and whether they are available in front of or behind the pharmacy counter. In the Consumer Health Product Framework, Health Canada acknowledged the need for a regulatory approach that will be flexible and responsive enough to adapt to rapid innovation, shifts in the health professional sphere, and the ever-increasing demand from the consumer for more self-care options and information on how to use these products safely and effectively.

U.S. Context

In 2014, CHPA contributed to a research to better understand how consumers navigate through the retail space to locate and select OTC products. The Consumer in-store Navigation and Decision Making Model for OTC Drugs describes the consumer self-selection process. Briefly, once a consumer enters a retail setting, they use signs to find the medication area of the store. Once in the correct area of the store, they use the aisle signs to locate the correct aisle according to therapeutic area. Then, the majority of consumers use a combination of brand name and trade dress (including colors, graphics and logos) to arrive at the correct shelf. Once at the relevant shelf, consumers examine the products available and look for the symptoms they need to treat and brand name as well as pricing before making an appropriate selection. The process of selecting an OTC significantly differs with the process for health practitioners selecting and dispensing prescription drugs.

New research into this process has shown that consumers use visual cues like the brand name, trade dress (colors, logos and graphics) as significant guide posts to help them navigate retail and select appropriate products. For example, the majority of consumers (63%) use the look of packaging to find what they need because they are familiar with it, the color/package/logo is recognizable, it’s easy to find, and it stands out. But this is not as important as the brand name, where (87%) used the brand name to find the product they needed. Also, the majority of consumers (76%) use the combination of the brand name (56% and trade dress (20%) to find the appropriate shelf (product indication) in a retail environment. Retailers are leveraging the role of these visual cues to simplify store layouts, and develop navigational and educational signage to improve the flow of the shop and consumer shopping experiences.

These findings describe the important role of brand names, colors/logos/graphics in the consumer selection process which regulators need to leverage when designing new policies, guidance and regulations.

20 Redfern M, Survey of Chronic and Minor Ailment Sufferers (2014)
regulations that impact these elements to avoid the potential for unintended impacts on consumer behavior.
Opportunities for Regulatory Alignment

Long term objectives (beyond 5 years)

Bilateral initiatives for regulatory cooperation

1. **Health Canada and the U.S. FDA Continue to collaborate through existing multi-lateral forums:** Health Canada and the U.S. FDA should continue to collaborate through existing multi-lateral forums like the Pharmaceutical Inspection Co-operation Scheme (PIC/S), International Conference on Harmonization (ICH), the International Pharmaceutical Regulators Forum (IPRF), and the International Coalition of Medicines Regulatory Authorities (ICMRA) to achieve closer cooperation with international jurisdiction. However, these efforts should not be considered a substitute or alternative to pursuing specific initiatives to achieve better alignment between Canada and the U.S.

   - Continuing to work on existing international commitments instead of addressing specific areas for cooperation between Canada and the U.S. will fail to achieve the RCC objectives. We are concerned that the opportunity will be lost to identify and address specific regulatory issues and challenges on both sides of the border, such as reducing or minimizing duplicative and costly retesting requirements.
   - Existing commitments through PIC/S to continue to share inspection schedules and to promote leveraging inspectional resources to maximize inspection coverage, while an important step, will fail to produce tangible benefits to trade uniquely between Canada and the U.S. as a part of the RCC objectives.
   - Continuing joint multi-lateral and joint inspections of foreign sites of common interest with other PIC/S members and exchanging information under the ICMRA remain an important step but will fail to achieve the benefits of enhanced efficiencies and reduced duplicative inspections that a specific commitment for mutual reliance between Canada and the U.S. would offer.
   - Continuing to participate on ongoing ICH guideline consultations is an important measure to ensure global alignment, but would miss opportunities to increase cooperation and remove barriers distinctly between Canada and the U.S.

2. **Health Canada and the U.S. FDA Institutionalize Regulatory Cooperation:** Long term, the RCC should take steps to institutionalize regulatory cooperation between Health Canada and U.S. FDA to ensure it is a permanent fixture of regulatory activity. Elements of such a system should include regulator opportunities for stakeholder engagement, transparency on deliverables and progress, new opportunities to add new ideas and expand work plans as well as regular evaluation of initiatives to ensure they have had the intended impact.

   - Regular opportunities for stakeholder engagement as a part of a public outreach plan to partner with industry and establish consistent routine of meaningful, two-way dialogue with stakeholders will help keep work plans on track and identify potential problems in a timely manner.
   - Increased transparency of RCC Working Group progress, departmental leads, and stakeholder submissions will ensure cooperation efforts are well documented and can progress over time.
• Integrating opportunities to add new ideas into RCC work plans instead of focusing on initiatives that are "low hanging fruit" would allow for identifying strategic, long term or tougher issues that need to be addressed, that could have global application.

• Introducing an evaluation component within RCC work plans will ensure the broad goals of imparting a tangible impact on trade are met and resources are focused on initiatives that achieve these goals.
Medium term objectives (3-5 years)

Unilateral initiatives for Health Canada to achieve alignment

1. **Canada integrates regulatory cooperation into the process for developing regulations**: Health Canada should work with Treasury Board to ensure each new regulatory consultation takes into account how the proposed regulation would impact harmonization with the U.S.
   - This would be a key step towards institutionalizing regulatory cooperating by ensuring that when new regulations are made in Canada that it would flag regulatory activities that may have a substantial impact on regulatory cooperation and RCC programs.

2. **Health Canada establishes a policy to enable the Canadian industry to attest to U.S. OTC Monographs**: As an important step towards securing greater alignment between Canadian and United States OTC product approval processes, Health Canada should create a policy to enable the Canadian industry to attest to the standards of the U.S. OTC monographs to achieve market authorization.
   - Most of the OTC products marketed in Canada and the U.S. contain the same ingredients and many of the products have identical names and formulations.
   - A key lesson from the RCC project to develop a joint monograph was that aligning individual monographs may not deliver significant and timely benefits to regulators or industry.
   - Enabling the Canadian industry to attest to U.S. monographs could help eliminate unnecessary costs and delays to trade as it more closely aligns with the industry process for product development and introduction.
   - Adopting such a policy would help to achieve the deliverable from the 2012 Work Plan to streamline costs for manufacturers and distributors and enhance consumer access to these types of therapeutic products in Canada.

Bilateral initiatives for regulatory cooperation

3. **Canada and the U.S. ratify the Trans-Pacific Partnership**: Canadian and U.S. Governments should be encouraged to ratify the Trans-Pacific Partnership.
   - As co-signatories of the Trans Pacific Partnership, both Canada and U.S. have negotiated provisions in Chapter 8 (Technical Barriers to Trade) that will encourage cooperation, implement mutual recognition of testing procedures and encourage unilateral recognition of testing results, as well as consider sector-specific proposals for cooperation.
   - Chapter 18 of the TPP Agreement would require co-signing parties to adopt provisions similar to the U.S. by providing three years of data protection for clinical research that support new uses, formulations or route of administration for existing drug products, including non-prescription drugs. However, these provisions are technically not required for countries that offer at least eight years of data protection for new chemical entities (ie. prescription drugs). Canada would be the only signatory to the TPP Agreement that would not be required to adopt these provisions and that does not already have similar protections for new clinical research to support existing products like OTCs like the U.S. Aligning Canada with its major trading partner by voluntarily adopting these provisions would stimulate growth in the consumer health products industry by protecting innovation.
4. **Health Canada and the U.S. FDA strengthen mutual reliance on drug GMPs:** Health Canada and U.S. FDA should renew their original commitment in the 2012 Work Plan to increase mutual reliance on each other’s routine surveillance of GMP inspection reports of manufacturing facilities for drugs and personal products rather than having to conduct duplicative inspections in the other country.

- Aligning inspection decisions is one of the most important initiatives to avoid unnecessary differences between Canada and the U.S.
- This would allow both governments to more appropriately reattribute limited inspection resources into international jurisdictions where there isn’t the same level of confidence, which would result in the biggest payoffs for regulators, mitigating the greatest potential risks to Canadian and U.S. consumers.
- In 2011, the FDA announced activities to collaborate with the European Medicines Agency to strengthen mutual reliance. As a part of this strategy, they moved beyond collaborative projects and began relying on each other’s inspection outcomes. This allows both jurisdictions to find greater resource efficiencies by deferring or waiving inspections to be done in each other’s territories if certain conditions are met. It is unclear why the FDA has chosen to pursue a distinct initiative towards mutual reliance with Europe, but not with Canada.
- The Canadian government is no longer pursuing Mutual Recognition Agreements in the area of pharmaceuticals but remains committed to identifying alternative mechanisms to reduce trade barriers.
- Health Canada has already taken the first step by accepting FDA inspection reports and deeming that they do not need to be reviewed by Health Canada.
Short term objectives (2016-2017 annual work plans)

Unilateral initiatives for Health Canada to achieve alignment

1. **Health Canada adopts regulatory provisions for data protection for non-prescription drugs:**
   Health Canada should commit to harmonize with the U.S. FDA and align with the global consensus on intellectual property protection by committing to opt in to Article 18.50 2 (a) of Chapter 18 (Intellectual Property) of the TPP Agreement that would provide three years of data protection for new clinical data to support new uses, formulations or routes of administration for existing drugs, including non-prescription drugs.
   - These provisions would harmonize and align with the 1984 the Hatch-Waxman Act, that calls for a three-year market exclusivity period submissions requiring clinical trials, which would include new indications for existing products. This provision has been a major driver of the Rx-to-OTC switch process in the United States, by providing an incentive to conduct research on potential consumer uses for established drugs.
   - Adopting data protection provisions would help the Canadian industry catch up to international leaders like the U.S. in switch. Canadians currently wait seven years to have access to a switch product after a switch has been introduced in the U.S.

Bilateral initiatives for regulatory cooperation

2. **Health Canada and the U.S. FDA achieve commitments from existing RCC work plans**

   Top priority of the RCC Technical Working Groups should be to ensure timely completion of the current work plan commitments including those summarized below. The Working Group should periodically report on progress, goals that have been met and prospective timelines for outstanding activities.

**Joint Monograph:** Health Canada and FDA should commit to consult on the finalized joint "Antihistamine for the Common Cold" monograph that was committed to in the 2011 Joint Action Plan and the 2012 OTC Work Plans.
   - We understand that a draft common monograph was completed in 2013 and is awaiting final internal approval. In accordance with the 2012 Technical Working Group Plan this monograph should have been consulted upon in 2013.
   - The U.S. regulatory process is holding back Canadian innovation, market access and increased consumer choice amongst safe and effective self-care options for the treatment of allergies and colds.
   - CHP Canada and CHPA do not support the development of additional joint monographs as this requires regulatory change in the U.S. thereby hampering stakeholder engagement and extending time lines to approval. Such monographs are guidances in Canada and can undergo consultation and approval in a more expeditious manner.

**Monograph System:** The FDA should continue its work in collaboration with stakeholders to coordinate and adjust their OTC monograph development process as stated in the Joint Forward Plan. The 2014 OTC work plan indicates the FDA is looking at their monograph system in the context of the Sunscreen Innovation Act and will share its work with Health Canada.
**Consumer Health Products Framework:** Health Canada should continue with their commitment to publish the Consumer Health Product Action Plan, which will include a path forward to develop a new risk-based set of regulations for non-prescription drugs. The 2014 work plan also proposed that Canadian monographs would be incorporated by reference into these new regulations for non-prescription drugs. Health Canada should also continue to achieve alignment of outcomes for a consistent approach to cosmetics, disinfectants, natural health products and non-prescription drugs which includes addressing product reclasifications.

**Continue Health Canada initiatives to improve regulatory convergence with FDA:** In the 2014 Pharmaceuticals Work Plan Health Canada committed to take steps towards regulatory convergence with the FDA. This includes a commitment to consider FDA product classification decisions, consider FDA guidance documents during the development of Canadian guidances, solicit feedback from the FDA on Canadian guidances, and notify the FDA about the finalization of Canadian guidances.

- Gradual alignment of Canadian guidances with FDA will streamline costs for manufactures.

**Cooperation on Sunscreens:** The 2015 Over-the-Counter Products Work Plan commits Health Canada to share its work with the FDA as they make improvements to the regulations of sunscreens. The FDA should re-commit to publishing a Final Guidance on Sunscreens in late 2016.

**Joint approaches to nanotechnology regulation:** Continue to advance the 2012 work plan of the Nanotechnology Working Group to ensure a consistent approach and common principles for the regulation of nanomaterials.

- Nanomaterials can be present in variety of consumer health products like sunscreens and medicated creams. As both Health Canada and FDA explore how to regulate and mitigate potential risks of nanomaterials, it is imperative that a consistent approach exists for industry in Canada and the U.S.

**Expansion of the Common Electronic Submissions Gateway:** Health Canada and U.S. FDA should continue their work, in consultation with stakeholders, to expand the scope of the Common Electronic Submissions Gateway for electronic submissions in both eCTD and non eCTD format in accordance with the 2012 and 2014 Work Plans.

- Expanding the scope to include submissions in non eCTD format would increase opportunities for industry to take advantage of this mechanism for dual filings for over-the-counter drug submission. Currently, the use of the Gateway for OTCs is limited primarily to the submission of serious Adverse Drug Reaction and international serious unexpected adverse reaction data.

3. **Health Canada and the U.S. FDA incorporate new initiatives into RCC work plans to address the medium and longer term goals**

**Health Canada and U.S. FDA adopt a policy to eliminate duplicative confirmatory testing:** Health Canada and the FDA should establish a policy to waive or minimize the regulatory requirements to quarantine and retest OTCs that are imported from facilities that have been inspected and licensed by the other regulator.
- As co-signatories of the Trans Pacific Partnership, both Canada and U.S. have negotiated provisions in Chapter 8 (Technical Barriers to Trade) that will encourage cooperation, implement mutual recognition of testing procedures and encourage unilateral recognition of testing results, as well as consider sector-specific proposals for cooperation.
- This policy would recognize equivalency of GMP testing of the other regulatory authority, as proposed in Chapter 8 (Technical Barriers to Trade) of the Trans-Pacific Partnership.
- It would enable GMP-compliant products that have been verified by Health Canada to be shipped directly to customers in the US, and vice versa.
- This policy would have a tangible impact on trade, as the costs of retesting products can range from $150,000-$190,000 per product, per shipment, depending on the type of testing required. These costs not only prevent small businesses from engaging in export but are significant barriers to large multi-national companies as well. Eliminating this added cost would have an impact on the order of hundreds of millions of dollars.
- This policy would benefit consumers in both countries by enabling faster access to a wider variety of safe and effective consumer health products for self-care.

Health Canada updates guidance to harmonize with the U.S. FDA approach recognizing how finished products flow through the global supply chain: Health Canada should revise Guide-0067 to harmonize with the FDA’s current approach for oversight of drugs imported for export where the drug is intended for a different owner.23

- Companies that perform contract packaging and labeling services for export markets must comply with Health Canada’s Guide-0067: Conditions for Provision of Packaging/Labelling Services for Drugs Under Foreign Ownership. The Guide assumes that when a foreign company uses a Canadian packager or labeler, the product will be marketed in the same country as the company of origin. Thus, the Guide does not take into account a now common scenario where a foreign-made product that is packaged and labeled in Canada may be destined for marketing in a different country.
- The Guide’s requirement for a foreign manufactured product to be returned to its foreign site after packaging and labeling in Canada creates significant administrative red tape for industry which creates millions of dollars in unnecessary shipping costs. For example, if a product is manufactured in Europe and is packaged and labeled in Canada, it would need to be shipped back to Europe even if the destination country for the product is the U.S. Shipping can be quite costly as manufacturers need to ensure their products are transported, handled and stored in a manner that mitigates risk of exposure to temperatures outside of labeled storage conditions to avoid any potential impact on the safety, quality and efficacy of the product. Moreover, the requirements of the Guide discourage foreign investment in Canadian packaging/labelling services, which can cost hundreds of Canadian jobs.
- In order to provide assurance that products are not being diverted, Health Canada should also accept documentation assuring that finished products are shipped according to the documented ownership of the product throughout the transaction at the point of product entry into and exit

from Canada. CHP Canada recommends that Health Canada consider harmonizing with the FDA’s current approach for the oversight of drugs imported for export where the drug is intended for a different owner.
Conclusion

The CHPA and CHP Canada support the objectives of the Regulatory Cooperation Council and the opportunities to more closely align the regulatory systems of Canada and the U.S. We look forward to a renewed commitment to the RCC by both governments in recognition of the value of deepening ties between our two countries. We appreciate the opportunity to consult with the RCC Senior officials and Technical Working groups to describe industry trends and key areas for enhanced cooperation such that regulators can plan strategically to ensure regulatory frameworks are not only aligned but are flexible and can adapt to new innovations and business realities. Now that both Canada and the U.S. have signed on to the Trans-Pacific Partnerships (TPP), we see the work of the RCC in a new light where the advancements aligning our regulatory systems can have broader far reaching impacts to enhance global trade. International trade agreements like the TPP are driving global consensus on regulatory cooperation. We view the RCC as an important opportunity to ensure Canada and the U.S. to not only keep up with this global movement but lead it, rather than getting left behind.