Priorities for Regulatory Alignment in the Consumer Health Product Industry

Submitted to the Regulatory Cooperation Council

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CHPA®

Consumer Health Products Canada | Produits de santé consommateurs du Canada

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Executive Summary

Consumer Health Products Canada (CHP Canada) and the Consumer Healthcare Products Association (CHPA) respectfully submit this brief to Treasury Board Secretariat of Canada and the U.S. Office of Information and Regulatory Affairs (OIRA) to provide industry input as the organizations develop the 2017-2018 Regulatory Cooperation Council (RCC) work plans.

In our April 2016 joint submission to the RCC, we provided an in depth review of the trends facing our industry over the past 10 years, and identified a series of short, medium and longer-term objectives to improve regulatory cooperation. We are happy to report that many of our recommendations have been addressed, particularly with enhanced efforts to incorporate regulatory cooperation into internal processes on both sides of the border and with continued work against previous RCC commitments. Since then, both governments have also signaled continued commitments for greater regulatory cooperation as a part of the North American Free Trade Agreement (NAFTA) renegotiations. As such, our recommendations for the RCC's 2017-2018 work plans identify the industry's top three strategic regulatory cooperation issues from a holistic sense, impacting the RCC work plans and NAFTA negotiations in the short term to reduce barriers to trade and investment between our two countries.

Harmonized regulatory data protection provisions within NAFTA	Mutual Recognition Agreement for drug GMPs	Joint Anti-Histamine Monograph
• Priority #1 • Short-term Goal • Unilateral initiative (Canada)	• Priority #2 • Short Term Goal • Bilateral initative	• Priority #3 • Short Term Goal • Unilateral intiative (USA)

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 Treasury Board Secretariat of Canada, Health Canada and the various U.S. FDA Technical Working Groups to support implementation of our proposed solutions.

Who we are

Consumer Health Products Canada

CHP Canada is the 120-year old national industry trade association that represents the companies that make evidence-based over-the-counter (OTC) medicines and natural health products (NHPs). 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 $5.8 billion dollar per year consumer health product industry represents about 50,000 OTCs and 20,000 NHPs and employs approximately 57,000 Canadians[1]. 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

CHPA is the 136-year old trade association representing the leading manufacturers and marketers of OTC medicines and dietary supplements that provide safe, effective and affordable therapies to treat and prevent many common ailments and diseases. Literally, from head to toe, OTCs and supplements are the trusted first line treatment for 240 million Americans every year and are recommended by healthcare providers to their patients for a range of health and wellness needs. These accessible, affordable and trusted medicines and supplements empower individuals and families to meet their everyday healthcare needs. 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.

Together, CHP Canada and CHPA represent 80 companies that manufacture, market and distribute OTC medicines and NHPs/ dietary supplements Canada and the U.S., with sales totalling over $58.3 billion USD[2] [3]in sales per year in North America.

[1] Conference Board of Canada, Healthy Growth: Estimating the Economic Footprint of the Fast Growing Consumer Health Products Industry (2015)
http://www.chpcanada.ca/sites/default/files/healthy_growth_final_report.pdf
[2] Grand View Research: Dietary Supplements Market to Reach $278.02 Billion by 2024 (June 2016)
http://www.grandviewresearch.com/press-release/global-dietary-supplements-market
[3] Neilsen Company OTC Retail Sales (1992-2016) https://chpa.org/OTCRetailSales.aspx

Opportunities for Regulatory Alignment in the 2018-2019 RCC work plans

1. Canada harmonizes U.S. regulatory incentives for innovation through NAFTA renegotiations

Priority #1

Short Term Goal

Unilateral Initiative (Canada)

Issue:

- Although Canada's $5.6 billion/ year consumer health product market ranks in the top 10 internationally, it is not a top 10 country for product innovation.
- Canada lags behind the U.S. regarding the introduction of new products by an average of 10 years due to: (1) a lack of regulatory incentives such as data protection; (2) administrative red tape causing delays in market access.
- These barriers to innovation are costing the Canadian Government, payers and individuals billions of dollars per year.
    - For example, proton-pump inhibitors (PPIs) to treat frequent heartburn were switched in the U.S. in 2003, and 11 years later in Canada. A recent report estimated the switch of PPIs would generate $709.9M in savings per year for governments (avoided physician visits and public drug plan coverage) employers, and private drug plans[4] - meaning this 11-year switch lag in Canada could have resulted in over $7 billion in avoidable costs. **(For more information see the report cited below)**
- Regulatory incentives to protect clinical data supporting new claims for existing drugs for three years, consistent with the U.S. approach and international consensus, should be integrated into the North American Free Trade Agreement.

Context:

- Innovators seek product approvals in multiple jurisdictions to offset the high costs associated with developing new products.
- Not providing incentives for innovators in Canada has resulted in certain switches never entering Canada- or doing so much later than in other countries. Switches in Canada very often occur a decade or more after they happen in the U.S. **(See Appendix 1, Annex 1).**
- The Canadian consumer health products industry responds to initiatives to encourage innovation. When the Canadian switch process was amended in 2013 to make the

[4] Conference Board of Canada "Value of Consumer Health Products: The Impact of Switching Medications to over-the-counter (March 2017)
http://www.chpcanada.ca/sites/default/files/files/8681_EcoImpactsRxTtoOTC_RPT.pdf

process more efficient (repealing Schedule F to the *Food and Drugs Act* in place of a Ministerial Prescription Drug List), it triggered a boom in switch. We have seen more switches in Canada since then compared to the past 13 years combined.

- Regulatory alignment for data protection provisions is needed between Canada and the U.S. to encourage innovation and avoid billions of unnecessary costs to Canadians per year.

Impacts:

- Harmonizing regulatory incentives for innovation would afford Canadians expedited access to enhanced product choices and result in a more efficient and effective use of resources for the Canadian government, private payers and individuals.

Support:

- Harmonized data protection for OTCs is supported by Canadian, U.S. and Mexican industry associations **(See Appendix 2)**

Objectives:

- Canadian and U.S. administrations, through the NAFTA renegotiations, seek a commitment from Canada to provide three years of data protection for new data required to support and provide regulatory approval for new uses, formulations or routes of administration for consumer health products (including “switch” products).

2. Health Canada and the U.S. FDA commit to a Mutual Recognition Agreement for drug Good Manufacturing Practices inspections

Priority #2

Short Term Goal

Bilateral Initiative

Issue:

- While both Canada and the U.S. have established Mutual Recognition Agreements (MRAs) with the European Union (EU), in 2014 the RCC stepped away from its own commitment to pursue an MRA as part of its original 2012 work plan.
- Between 2015 and 2016, this lack of an MRA has cost both governments as much as $17.3 million in unnecessary, duplicative inspections, diverting finite inspection resources away from areas of the world that may pose a much higher risk. **(For more information, See Appendix 3).**
- An MRA for drug GMPs would establish Canadian and U.S. Drug GMP regulations as equivalent and allow a shared reliance on each other's inspections and decisions.

Context:

- Global multi-national companies are seeking better global alignment and regulatory harmonization regarding manufacturing processes.
- An MRA for drug GMPs between Canada and the U.S. would better align with how products are manufactured and flow through global supply chains.

Impacts:

- An MRA would: result in timelier market access for Canadians and Americans, reduce costs to industry and consumers, lead to a more effective use of inspection and administrative resources, and increase product quality in jurisdictions where saved inspection resources have been reattributed.
    - For example, it is estimated that the RCC OTC sunscreen pilot that eliminated the duplicate confirmatory and ID testing for these products could result in over $32 Million in savings for the industry annually **(For more information, See Appendix 4).**
- CHPA and CHP Canada's recommendation is supported by the prescription drug industry, generic drug industry, and cosmetics industry.

Objectives:

- Health Canada and U.S. FDA should formally commit to establishing an MRA for drug GMP inspections.
- The RCC formally recognize the past years' work together as being part of the "mutual reliance phase" to expedite the transition time necessary to establish such an MRA.

3. Health Canada and the U.S. FDA finalize the Joint monograph "Anti-histamine for the common cold"

Priority #3

Short Term Goal

Unilateral Initiative (USA)

Issue:

- In their 2012 RCC work plan, Health Canada and the U.S. FDA committed to developing a joint monograph "Anti-histamines for the common cold." The development work was completed in 2013 but it has not been finalized due to regulatory and administrative red tape associated with the U.S. regulatory consultation process.
- This joint effort has actually imposed U.S. regulatory barriers on Canada instead of eliminating them, preventing Health Canada from finalizing an urgently needed monograph in Canada.
- Competing regulatory priorities at the FDA have deprioritized the joint anti-histamines monograph, halting any progress towards the necessary U.S. Federal Register publication and consultation.
- This monograph would stimulate innovation and directly result in faster access for new safe and effective product options for Canadians and Americans seeking to treat their cold and allergy symptoms.

Context:

- As a result of this experience with the joint monograph in 2013, the RCC shifted its commitment in this area to acknowledge FDA's work collaborating with stakeholders to coordinate and adjust their OTC development process. As a part of ongoing monograph reform discussions, the FDA has publicly stated that their monograph development system is in need of reform.
- 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[5]. 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[6]. If OTC medicines were not available, more consumers would seek prescriptions, causing a surge in office visits requiring 56,000 additional full time medical professionals.[7] On average, it is estimated that for every dollar spent on OTCs, it saves the U.S.

[5] Booz & Co The value of OTC medicines in the United States (2012) http://www.yourhealthathand.org/images/uploads/The_Value_of_OTC_Medicine_to_the_United_States_BoozCo.pdf

[6] Lipsky, Northwestern University (2004) http://www.yourhealthathand.org/images/uploads/Affordability-Jun2011-updated2.jpg

[7] Booz & Co The value of OTC medicines in the United States (2012) http://www.yourhealthathand.org/images/uploads/The_Value_of_OTC_Medicine_to_the_United_States_BoozCo.pdf

healthcare system $6-7.

- A recent U.S. study showed that more Americans are suffering from seasonal allergies and are choosing OTCs instead of prescription medications. According to the research, approximately 28 percent of Americans in 2015 reported that they suffer from seasonal allergies, with the majority of allergy sufferers (60 percent) saying they choose OTC medicines alone as their preferred treatment method. This represents a 20 percent increase from 2009. The study also showed 75 percent of allergy sufferers purchased an OTC medication either on its own or in addition to a prescription treatment in 2015, compared to just 66 percent in 2009, suggesting that consumers have adjusted their behavior as more OTC options have become available over the past several years.[8]

Impacts:

- The finalization of a joint anti-histamines monograph would: Result in increased product choices, faster market access and decreased costs for Canadians and Americans seeking to treat their cold symptoms, and lead to more efficient and effective use of industry and government resources.

Support:

- Finalization of the joint anti-histamines monograph is supported by Canadian and U.S. industry.
- 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.

Objectives:

- FDA should commit to prioritize and advance the public consultation of the joint "Anti-histamines for the Common Cold" monograph with publication of a Proposed Rule in the Federal Register in 2018.

[8] Nielsen and CHPA, Assessing Consumer Benefits of Allery Rx-to-OTC switches file:///C:/Users/kristin/Downloads/CHPANielsen_Allergy_OTC_White_Paper.pdf

Conclusion

The topic of regulatory cooperation between Canada and the U.S. has found a new forum outside of the established RCC, and has been elevated and integrated as negotiating objectives into recent NAFTA negotiations. We perceive this to be a positive sign of deepening relationships between our two countries. At the same time, this raises the need for a coordinated and informed holistic effort to drive towards regulatory cooperation objectives through different mechanisms. As such, we trust this brief, which summarizes our regulatory cooperation objectives for both the NAFTA trade negotiations and the RCC, will provide insight into strategic industry priorities towards tangible trade benefits.

Appendix I: Briefing note: Data Protection & NAFTA

(For Information only)

Summary:

- Although Canada's $5.6 billion/ year consumer health product market ranks in the top 10 internationally, it is not a top 10 country for product innovation.
- Canada lags behind the United States (U.S.) regarding the introduction of new products by an average of 10 years due to: (1) a lack of regulatory incentives such as data protection; (2) administrative red tape causing delays in market access.
- CHP Canada is recommending that Canada provide three years of data protection to protect data used to support regulatory approval for the switching of existing prescription drugs to non-prescription status, as well as for new uses for existing non-prescription drugs, consistent with the U.S. approach and international consensus.

Issue:

Manufacturers of non-prescription drugs and natural health products innovate primarily by investing in research that supports new evidence-based uses for existing products, often resulting in the switch of prescription products to non-prescription status. However, investments in product development and research do not guarantee an opportunity to recuperate business costs, as 75% of proposed consumer health products never proceed to launch.

Global companies prioritize new product development in countries where innovative products are most likely to succeed. While in the early 1980's Canada had among the broadest selections of over the counter medicines in the developed world, the country has lost its leader status and is lagging significantly behind its trading partners largely due to two main barriers that other countries have addressed: 1) A lack of data protection for innovators, and 2) Administrative red tape that creates uncertainties and causes significant delays to market.

Innovators seek product approvals in multiple jurisdictions to offset the high costs associated with developing new products. Not providing incentives for innovators in Canada has resulted in certain switches never entering Canada- or doing so much later than in other countries. Switches in Canada very often occur a decade or more after they happen in the U.S. (see Annex A for a list of products and their current switch status between the U.S. and Canada).

Background/Current Status:

Data Protection

All Canadian regulations are required to comply with the Government of Canada's international agreements: the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and North American Free Trade Agreement (NAFTA). Specifically:

- In Section 7 Article 39 of TRIPs Canada agreed to *protect undisclosed data* submitted in support of new chemical entities that involves considerable effort against *unfair commercial use*.
- Article 1711 of NAFTA builds on the TRIPS agreement and establishes *a reasonable period* of time as not less than 5 years for which data should be protected for new chemical entities.

Canada's current approach to compliance with NAFTA and TRIPs is set out in Division 8 of the *Food and Drug Regulations,* which establishes a period of 8 continuous years of data protection for "innovative drugs," (new chemical entities). However, evidence to support new uses for existing drugs, such as that required for Rx-to-OTC switches, does not benefit from any form of data protection. In the time since the current NAFTA and TRIPS provisions were established, the thinking on intellectual property protection has evolved to include this type of evidence. For example:

- In the U.S. the Hatch/Waxman Act establishes a period of 5-years of market exclusivity (not just data protection) for new chemical entities, and additional 3-year periods of market exclusivity for new claims on existing products where new clinical data was essential for the approval of the application. This additional 3 year period, which does not have to be concurrent to the original 5-year protection, has been a major driver of the Rx-to-OTC switch process in the United States, as it provides an incentive for manufacturers to conduct research on potential consumer uses for established prescription drugs.

- In the EU, 10-years of market exclusivity is available for new chemical entities, and an additional, consecutive 1-year of market exclusivity is provided for new clinical data to support new claims on existing products.
- Chapter 18 of the former Trans Pacific Partnership Agreement (TPP) recognized the value of new intellectual property related to established chemical entities, by requiring signatory countries to provide three years of data protection for clinical research that supported new uses, formulations or route of administration for existing drug products, including non-prescription drugs.

Ingredient based-switch

Canada's current system for switching prescription drugs to OTC status is ingredient based, rather than product based. The result of this is that the "switch" applies to all competing products with the same formulation at the same time. Because the act of switching an ingredient is considered a technical regulation as per the World Trade Organization's (WTO) Technical Barriers to Trade Agreement, Health Canada must notify the WTO and its member countries and delay the finalization of the switch for at least 6 months in order to give enough time for competitors who also employ this ingredient in their products to adapt to the change. This is not the case in other countries, where switches are product-based, affecting only one manufacturer, and therefore do not require WTO

notification. **In the absence of any form of data protection**, this six-month delay, combined with the delays associated with drug scheduling and the shorter federal approval time for second entry products, means that competing products often hit store shelves before the innovator's product has had time to establish itself, and sometimes even get there first.

Opportunities:

The upcoming renegotiations of NAFTA provides a unique opportunity to better align data protection provisions with Canada that would align with current thinking on intellectual property protection with respect to medicines and support innovation and growth in the consumer health product sector.

Recommendations

CHP Canada recommends that the U.S. administration, through the NAFTA renegotiations, seek a commitment from Canada to provide three years of data protection for new data required to support and provide regulatory approval for new uses, formulations or routes of administration for consumer health products (including "switch" products).

ANNEX A

1. Switch Lag (U.S. vs Canada):

Ingredient	Product Category	U.S. brands	U.S. OTC Approval	Status in Canada	Date of OTC approval in Canada	Switch lag in Canada
nicotine polacrilex troche/lozenge (NDA)	smoking cessation	Commit	31/10/2002	switched	22/06/2006	4
omeprazole magnesium	acid reducer to treat frequent heartburn	Prilosec OTC	20/06/2003	switched	17/09/2014	11
triamcinolone acetonide	Allergic rhinitis	Nasacort Allergy 24 hr spray	11/10/2013	switched	24/02/2016	4
esomeprazole magnesium	Frequent heartburn	Nexium 24 hr	28/03/2014	Switched	10/08/2016	3
fluticasone proprionate	Allergic rhinitis	Flonase	23/07/2014	Switched	26/08/2016	2
naproxen	Pain reliever	Aleve	1994	Switched	19/05/2009	15
minoxidil 5%	Hair regrowth treatment	Rogaine	1996	Switched	22/08/2014	18
hydrocortisone 1%	Anti-itch	Neosporin	1991	Switched	26/12/2014	23
Average switch lag						**10 years**

2. Products not yet available OTC in Canada, but are OTC in U.S.

Ingredient	Product Category	U.S. brands	U.S. OTC Approval	Status in Canada	How long have they been available OTC in the U.S.?
ketotifen	antihistamine eye drops	Zaditor	19/10/2006	Rx	11
terbinafine	Topical antifungal	Lamisil Derm gel	24/7/2006	rx	11
orlistat	weight loss aid	alli	7/2/2007	Rx	10
lansoprazole	Acid reducer to treat frequent heartburn	Prevacid 24 Hr	18/05/2009	Rx	8
oxybutynin	Overactive bladder	Oxytrol for women	24/1/2013	Rx	4
budesonide	Allergic rhinitis	Rhinocort Allergy Spray	23/3/2015	Rx	2
adapalene 1%	Anti-acne	Differin Gel	08/07/2016	Rx	1

Appendix 2: Joint CHP Canada, CHPA and AFAMELA Letter on NAFTA objectives

June 12, 2017

Mr. Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Comments on Negotiating Objectives Regarding Modernization of the North American Free Trade Agreement with Canada and Mexico, Docket Number USTR-2017-0006

Dear Mr. Gresser:

Consumer Health Products Canada ("CHP Canada"), the Consumer Healthcare Products Association ("CHPA"), and La Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C. ("AFAMELA"), and their members welcome this opportunity to provide comments on negotiating objectives regarding modernization of the North American Free Trade Agreement ("NAFTA"), pursuant to the request for comments published in the Federal Register on May 23, 2017 (82 Fed. Reg. 23699).

CHP Canada, CHPA, and AFAMELA are the leading health care products associations of Canada, the United States, and Mexico, respectively, representing manufacturers of over-the-counter medicines such as pain relievers and allergy medications, and natural health products such as vitamins and supplements. The three associations are taking the unusual step of jointly requesting that the United States Trade Representative ("USTR") include in its negotiating objectives for the modernization of NAFTA the incorporation of data protection for new claims on existing healthcare products where new clinical data is essential to obtain approval to "switch" from prescription products to non-prescription status ("Rx-to-OTC").

Specifically, we believe the United States should include as a negotiating objective securing a three-year period of data protection period for Rx-to-OTC switches, a period that reflects the standard of protection found in United States law, namely the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). We make this joint submission because we believe the benefits of this policy change are so compelling to all stakeholders in all three countries.

Current Canadian law establishes a period of eight continuous years of data protection for new chemical entities, but data to support new uses for existing drugs, such as that required for Rx-to-OTC switches, does not benefit from any form of protection. Furthermore, Canada's current system for Rx-to-OTC switches is ingredient based, rather than product based. Therefore, the act of switching an ingredient is considered a technical regulation under the World Trade Organization's

("WTO") Technical Barriers to Trade ("TBT") Agreement, triggering a mandatory notification and comment period. This additional process, which is not required where switches are product based as in the United States, delays the finalization of the switch for at least six months.

The combination of Canada's lack of data protection for Rx-to-OTC switches with the additional delays resulting from an ingredient-based system has a stifling effect on innovation and on Canadian consumer's access to OTC medicines. This is because healthcare companies are not incentivized to invest in the additional research necessary to achieve Rx-to-OTC switches, as the lengthy approval process means that competitors often reach the market at essentially the same time as the innovator. Ensuring the same standard of protection for Rx-to-OTC switches as provided in the United States will encourage innovators to actively pursue Rx-to-OTC switches in Canada, resulting in significant benefits to all stakeholders, including governments, pharmaceutical companies, and consumers.

Attached to this letter, we provide a study conducted by the Conference Board of Canada regarding the impact of Rx-to-OTC switches. As indicated in the study, the economic value of switching just three categories of products would result in $1 billion in savings. These savings come in the form of decreased costs for payers of prescription medicine, such as provincial governments, employers, private drug plan sponsors, and individuals who currently do not have access to prescription drug coverage. Pharmaceutical companies also stand to gain as they are incentivized to pursue Rx-to-OTC switches, which will give these companies access to a broader OTC market. In fact, an analysis of the effect of switching nine drug categories found that use of the drug increased by 30 percent following the first switch. Most importantly, Rx-to-OTC switches act as an important policy tool for increasing access to medicines. OTC medicines are easier, faster, and more convenient to obtain, allowing consumers to take greater control of their health care decisions. Greater access to OTC medicines also reduces health care costs generally by allowing consumers to self-medicate rather than visit the doctor for routine issues.

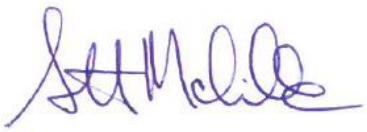
In short, providing data protection for Rx-to-OTC switches in Canada will lower the cost of medicines, lower health care costs more generally, increase access to medicines, increase market access for health care companies, and bring Canadian intellectual property law up to the standard in United States law. This presents one of those truly rare issues where all stakeholders unambiguously stand to benefit from a policy change.

We firmly believe that the incorporation of a 3-year data protection period for clinical data essential to obtain approval for Rx-to-OTC switches in Canada falls squarely within the goals of modernizing NAFTA, and will better align Canada's data protection provisions with those of the United States. We therefore respectfully request that USTR include this important

issue in its negotiating priorities.

Respectfully submitted,

Karen Proud
President
Consumer Health Products Canada



Scott Melville
President and CEO
Consumer Healthcare Products Association

Héctor Bolaños Varela
Executive Director
La Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C.

Appendix 3: Briefing Note: Mutual Recognition Agreement for pharmaceutical good manufacturing practices between Canada and the U.S.

(For Information only)

Summary:

- While both Canada and the U.S. have established Mutual Recognition Agreements (MRAs) with the European Union (EU), in 2014 the Canada-U.S. Regulatory Cooperation Council (RCC) stepped away from its own commitment to pursue an MRA as part of its original 2012 work plan.
- Between 2015 and 2016, this lack of an MRA has cost both governments as much as $17.3 million in unnecessary, duplicative inspections, diverting finite inspection resources away from areas of the world that may pose a much higher risk.
- The renewed commitment in the Canada-U.S. RCC provides the ideal opportunity to gain a formal commitment from the Canadian and U.S. governments to establish an MRA and to immediately enter the "Mutual Reliance" phase, allowing Health Canada and FDA drug inspectors to rely upon information from drug inspections conducted within each other's borders.

Background & Context

Consumer Health Products Industry:

Consumer health products are items that are used every day to maintain health and manage minor ailments. These products include over-the-counter drugs such as pain relievers and allergy medications, and natural health products such as vitamins and supplements.

The Consumer Healthcare Products Association (CHPA) is the 136-year old trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements in the United States. Consumer Health Products Canada (CHP Canada) is the Canadian national industry association representing manufacturers of evidence-based non-prescription medicines (OTCs) and natural health products (NHPs).

In the U.S, the OTC industry has grown over 160% in the last 10 years and is estimated to generate $40 billion in sales. Research has shown that 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. In Canada, domestic and international sales of consumer health products have also increased rapidly over the last decade, compared to overall retail sales. From 2004 to 2014, total retail sales across the country grew at an average annual pace of 3.8 per cent while consumer health products sales

increased by 4.2 per cent per year. In 2014, domestic retail sales of consumer health products were valued at $5.6 billion, while exports were estimated at $1.5 billion. Between 2004 and 2014, exports of these products nearly doubled - an increase of almost three-and-a-half times the growth in overall exports. Overall, the Canadian industry makes a $5.8 billion contribution to GDP and supports almost 57,000 jobs.

Issue

Many of CHPA's and CHP Canada's and members are global multi-national companies based in the U.S. who are seeking better global alignment and regulatory harmonization regarding manufacturing processes.

Mutual Recognition Agreements (MRAs):

The role of an MRA for good manufacturing practice (GMP) inspections is to encourage greater international harmonization, make more efficient use of inspection capacity and reduce duplication. Canada has an MRA with the E.U. for drug GMP inspections, which for some EU states began in 2003. This allows both regulators to rely on each other's inspections, reduces duplications, lowers costs and allows resources to be focused on areas of the world the may pose greater risk.

The 2012 Canada-U.S. Regulatory Cooperation Council (RCC) Work Plan committed Health Canada and the U.S. FDA 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 each country. However, in the 2014 RCC Work Plan, Health Canada and the U.S. FDA backed away significantly from this commitment and instead decided to simply continue to engage in existing multi-lateral forums on drug GMP inspections.

At the same time as the RCC was downgrading its joint commitment, the U.S. FDA and the E.U. were engaged in a mutual reliance initiative collaborating to evaluate the way they each inspect drug manufacturers and assess the risk and benefits of an MRA. In March 2017, the U.S. FDA and the E.U. announced the MRA for drug GMP inspections.

Current Status

Despite the fact that OTCs are manufactured in Canada and the U.S. to similar GMP requirements and similar protections, and despite the fact that both Canada and the U..S have entered into MRAs with the E.U., the lack of an MRA between Canada and the U.S. means that both regulators need to inspect the same facility making products destined for each country. Not only are facilities being inspected twice, when products cross the border, the same confirmatory testing needs to be repeated, adding costs, discouraging trade and creating delays for consumers to access new products.

Currently, the RCC work plans only commit Health Canada and the FDA to continue participation in existing multi-lateral forum such as 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 other jurisdictions. While this commitment is important, not addressing specific areas for cooperation between Canada and the U.S. undermines the attainment of the RCC objectives to produce tangible benefits to trade between Canada and the U.S.

Considerations & Impacts

Policy Alignment:

- Pursuing an MRA for GMP inspections between Canada and the U.S. aligns directly with the objectives of the RCC. These objectives continue to be a commitment from President Donald J. Trump and Prime Minister Justin Trudeau as evidenced in a recent joint statement, as well as the U.S. government direction to reduce regulatory burden and control regulatory costs.
- Aligning inspection decisions is one of the most important initiatives to avoid unnecessary differences between Canada and the U.S. It would create shared, tangible regulatory outcomes that are business-friendly, reduce costs, and increase economic efficiency without compromising health, safety and standards.

In 2012, the U.S. Congress passed the *Food and Drug Administration Safety and Innovation Act* giving the FDA authority to enter into agreements with foreign regulators to recognize drug inspections that are capable of meeting U.S. requirements.

In the 2011 *Special Report: Pathway to Global Product Safety and Quality*, the FDA outlined their vision for the next decade recognizing that product safety and quality no longer begin or end at the border. This report stated that it is not feasible for the U.S. FDA to inspect every high risk international pharmaceutical facility and that there is a need 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. Health Canada committed a similar approach to collaborate with international regulatory partners in a 2015 *Annual Inspection Summary Report.* Over 80% of health products are imported into Canada, and as the global supply chain continues to expand with companies producing more products around the world, Canadians are exposed to greater risks via products manufactured in countries with little regulatory oversight.

Resource Implications:

- An MRA for drug GMP inspections between Canada and the U.S. would result in cost savings for both regulators, without compromising health and safety. This would allow both governments to more appropriately reallocate limited inspection resources to international jurisdictions where there isn't the same level of confidence, resulting in an enhanced ability of regulators to mitigate the greatest potential risks to Canadian and U.S. consumers.

Savings to regulators and industry due to elimination of duplicative inspections

- The FDA inspected 26 Canadian facilities in 2016 and 35 in 2015 that were already licensed and inspected by Health Canada.
    - Based on the annual generic pharmaceutical user fees for foreign finished dosage form facilities, (which cover 56% of the recovery costs for personnel and a premium

for foreign inspections) we estimate the cost of one inspection and administrative licensing can range from $59,000- $273,000 USD.
    - We estimate the inspections carried out over the last two years cost the FDA and the industry each: $1.5M- $7M USD in 2016 and $2M-$9.5M USD in 2015.
    - In 2015-2016, out of the 28 E.U. countries that the U.S. has just established an MRA with, Canada ranks third for most FDA inspections behind Germany (120 FDA inspections) and Italy (77 FDA inspections) during that same time, indicating an MRA with Canada would provide value compared to EU countries. If these resources for 61 foreign FDA inspections were instead spent in India or China during that same time period, it would represent a 31% and 24% increase in inspection capabilities within these counties, where oversight is most needed.

- Health Canada inspected 5 U.S. facilities in 2016 and 2 in 2015.
    - Based on the annual 2016 fees for Drug Establishment Licenses (which cover the review of an application, annual reviews, amendments and domestic and foreign inspections) and with domestic inspections occuring every 3 years, we estimate the cost for one inspection and administrative licensing to range between $25,000-$120,000 CDN, which represents 61% of the recovery costs for Health Canada.
    - We estimate the inspections conducted over the last two years cost Health Canada and the industry each: $125,000-600,000 CDN in 2016 and $50,000-$240,000 CDN in 2015. This represents approximately 18% of Health Canada's limited resources for foreign inspections, as a total of 11 and 28 inspections took place in 2016 and 2015 respectively.

- Although industry would need to continue to pay the above licensing fees for foreign facilities regardless of whether the site is in an MRA country, tangible savings would result due to the elimination of duplicate inspections. Preparation for and conducting an inspection represents investment of 660-1040 extra person hours, beyond daily responsibilities.

Savings to industry due to elimination of duplicative confirmatory testing

- With an MRA, it would no longer be necessary to quarantine and immediately retest products coming from a licensed facility in the other country. The costs of retesting products can range from $120,000-$190,000 per product per shipment annually, depending on the type of testing required. As a result of these costs, some products are never launched in Canada due to limited availability of Canadian testing labs that have completed verification of the required test methods. Eliminating duplicative testing will also shorten release times, enabling consumers on both sides of the border faster access to new treatment options.

Review Resource efficiencies

- With an MRA, only a valid Certificate of Compliance from the other regulator is required to demonstrate site compliance, which requires minimal review. This would eliminate the need to review large files, including Exit Inspection Reports, responses, SOPs and Site Master Files.

- Annually, Health Canada receives over 400 Certificates of Compliance from its MRA partners and reviews close to 500 inspection reports for foreign sites not in MRA countries.

Recommendation:

- CHP Canada and CHPA's recommendation (which is supported by the prescription drug industry, generic drug industry, and cosmetics industry) is that, under the Canada-U.S. RCC, both governments formally commit to establishing an MRA for drug GMP inspections.
- We further recommend that the RCC formally recognize the past years' work together as being part of the "mutual reliance phase" and therefore expedite the transition time necessary to establish such an MRA.

Appendix 4: Estimated savings to the Canadian industry by eliminating duplicative confirmatory and ID testing for products imported from the U.S. as a part of the OTC sunscreen pilot

Element	Estimated Cost per DIN/ year	Extrapolated costs for 237 OTC DINs participating in the pilot (11 participating companies)	Extrapolated costs for all 1,258 approved and marketed OTC DIN sunscreens (representing 166 companies)
Assumptions			
# of Shipments/ year	5 Shipments/ year	5 Shipments/ year x 237 DINs = 1,185 Shipments/ year	5 Shipments/ year x 1,258 DINs =6,290 Shipments/ year
Average batch size/ shipment	55,000 Units	55,000 Units x 1185 = 65,175,000 Units	55,000 Units x 6,290= 345,950,000 Units
# of pallets/ shipment	8 pallets/ shipment	9,480 pallets	50,320 pallets
Direct costs			
Annual Confirmatory testing and ID testing per shipment	$1,500/shipment X 5 shipments = **$7,500**	$1,500/shipment X 1,185 shipments= **$1,777,500**	$1,500/shipment X 6,290 shipments= **$9,435,000**
Average # days stock can be released earlier due to lack of confirmatory testing/ shipment	27 days X 5 shipments = 135 days saved	27 days X 1,185 shipments = 31,995 days saved	27 days X 6,290 shipments = 169,830 days saved
Cost savings for average storage/warehouse costs for 1 month of product quarantine for 1 shipment (of 8 pallets)	$80 X 5 shipments = **$400**	$80 X 1185 shipments = **$94,800**	$80 X 6,290 shipments = **$503,200**
Storage cost savings due to avoided Known Laboratory Errors (KLE) by CDN contract who infrequently test a certain dosage form) results in average delay of 1 week	($80/4= $20 per shipment) X 3 KLE/ year= **$60**	3 KLE/year X ($20/ shipment) X 1,185 shipments= **$71,100**	3 KLE/year X ($20/ shipment) X 6,290 shipments= **$377,400**
Total direct cost savings for pilot participants	**$7,960**	**$343,400**	**$10,315,600**
Indirect costs			
Costs of 1 month storage when establishing safety stock levels	**$400**	$400 x1185 shipments = **$474,000**	$400 x 6,290 shipments =**$ 2,516,000**
Costs due to management and oversight of outsourced/third party testing laboratories	2 FTE X $60,000= **$120,000**	2 FTE x 11= 22 FTE, or **$1,320,000**	2 FTE x 166 Companies= 332 FTE, or **$19,920,000**
Potential indirect cost savings for pilot participants	**$120,400**	**$1,794,000**	**$22,436,000**
Total possible savings of direct and indirect costs for sunscreen pilot participants	**$128,360**	**$2,137,400**	**$32,751,600**