July 18, 2017

NAFTA Consultations
Global Affairs Canada
Trade Negotiations — North America (TNP)
Lester B. Pearson Building
125 Sussex Drive
Ottawa, ON  K1A 0G2

Re: Renegotiation and modernization of the North American Free Trade Agreement (NAFTA)

Consumer Health Products Canada (CHP Canada) is the Canadian national industry association representing manufacturers of evidence-based non-prescription medicines and natural health products (NHPs). In 2014, domestic retail sales of consumer health products were valued at $5.6 billion, while exports were estimated at $1.5 billion. Overall, the Canadian industry makes a $5.8 billion contribution to GDP and supports almost 57,000 jobs. For further information on the industry’s economic footprint in Canada, please see the attached report from the Conference Board of Canada [Attachment A].

CHP Canada recommends that modernization of the NAFTA include two specific provisions, one related to the chapter on intellectual property, the other to the proposed new area of regulatory coherence.

1. **Data Protection for Rx to OTC Switch**

   The “RX to OTC Switch” is a process through which a prescription drug (Rx) is made available over-the-counter (OTC), after a thorough review of the evidence supporting such availability is conducted by Health Canada. Rx to OTC switches, in addition to improving consumer access to safe and effective therapies, have been demonstrated to have significant positive economic impacts, on both the healthcare system and the broader economy, as well. A recent report by the Conference Board of Canada [Attachment B] estimated that Rx to OTC switches in just three categories of medicines could lead to over $1 billion in annual savings from lowered drug costs ($458 million), reduced unnecessary doctor visits ($290 million) and improved labour productivity ($290 million).

   Unfortunately, Canada significantly lags our major trading partners, including the United States, when it comes to Rx to OTC switch. Over the last ten years, such switches have occurred, on average, seven years later in Canada than in the United States, and nine years later than in the United Kingdom. This lag is costing the Canadian healthcare system and the broader economy billions of dollars. One of the key reasons for this lag is that, unlike the United States and the
European Union, Canada offers no regulatory data protection for the evidence manufacturers submit in support of an Rx to OTC switch. For a fuller exploration of the role of data protection in closing Canada’s performance lag on Rx to OTC switch, please see the attached briefing note on the subject [Attachment C].

CHP Canada and our American and Mexican counterpart organizations, the Consumer Healthcare Products Association (CHPA) and the Asociación de Fabricantes de Medicamentos de Libre Acceso (AFAMELA), have submitted a joint position statement to the Office of the United States Trade Representative [Attachment D], calling on the United States to seek a new intellectual property provision on regulatory data protection for Rx to OTC switches, in line with current US law.

Recommendation:
That modernization of the NAFTA chapter on intellectual property protection include a provision for three years of regulatory data protection for new clinical information submitted to secure non-prescription marketing approval of a previously approved prescription pharmaceutical product.

CHP Canada believes that modernizing NAFTA is an excellent opportunity to drive greater regulatory coherence throughout the health product sector in participating states. Manufacturing of consumer health products is highly integrated in the NAFTA zone, with many companies both exporting to and importing from all three nations. Canada and the United States, in particular, have very similar regulatory requirements around good manufacturing practices that should facilitate this trade, yet continue to duplicate regulatory inspections and product testing in the absence of a MRA. These duplicate inspections and product testing, described in detail in the attached briefing note on the subject [Attachment E], are very costly to both the industry and taxpayers in each respective country.

Recommendation:
As the health product regulators in both Canada and the United States have MRAs with their European Union counterparts, priority should be given to establishing such an agreement between Health Canada and the US Food and Drug Administration.

Respectfully submitted,

Karen Proud
President
Healthy Growth
Estimating the Economic Footprint of the Fast Growing Consumer Health Products Industry

Presented to:
Consumer Health Products Canada

The Conference Board of Canada – 2015
Prepared by: Alicia Macdonald and Matthew Stewart
Healthy Growth—Estimating the Economic Footprint of the Fast Growing Consumer Health Products Industry

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Acknowledgements

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Healthy Growth—Estimating the Economic Footprint of the Fast Growing Consumer Health Products Industry

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Executive Summary

Consumer health products are items that we use 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 health products industry, which includes wholesalers and retailers selling consumer health products and manufacturers involved in their production, has seen substantial growth over the last decade and has developed into a notable contributor to the overall economy. The goal of this report is to estimate the industry’s current economic footprint and measure its contribution to the Canadian economy.

Compared to overall sales growth, Canada’s domestic and international sales of consumer health products have increased rapidly over the last decade. 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, after a decade of phenomenal growth, 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. The relative performance of the sector is even more impressive compared to Canada’s total non-energy exports, which have managed almost no growth over the last decade.

Combined international and domestic sales of consumer health products are estimated at $7.1 billion in 2014, and the industry directly created $2.7 billion in GDP through manufacturing activities and wholesale and retail sales. However, the impact of the industry extends beyond its direct impacts to support many other industries by purchasing products and services for its production process. The industry directly employs 30,300 employees in manufacturing and the wholesale and retail trade sectors, and supports an additional 14,500 employees through its supply chain. These employees also contribute to the economy as they spend their income. Combining these three impacts provides us with an estimate of the total economic footprint of the consumer health products industry in Canada, which is valued at $5.8 billion in GDP and supports almost 57,000 jobs.

The industry generates income for the following stakeholders:

- $3.2 billion in household income;
- $848 million in corporate profits;
- $518 million in personal income taxes;
- $288 million in corporate income taxes; and
- $606 million in sales taxes.
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1. Introduction

This research explores the impact that the consumer health products industry has on Canada’s economy. The industry encompasses the items individuals use for self-administered health care such as over-the-counter medicines and natural health products. Sales of these products over the last decade have grown faster than overall retail spending and represented just over one per cent of all retail spending in the country in 2014.

This report quantifies the impact of spending on and exports of consumer health products on the Canadian economy. The first part of this study estimates the size of the industry and its direct impact on the economy and then, using standard econometric techniques, estimates the complete economic footprint of the industry, which is the total of its direct, indirect and induced economic impacts. The scope of this study is to focus on only the impacts associated with consumption and exports. As such, it does not attempt to quantify factors such as the benefits accruing to the economy through the industry’s role in helping to maintain a healthy population or reducing the burden on healthcare systems. For example, the study does not attempt to estimate the impact of reduced employee absenteeism due to one’s ability to self-treat minor ailments using consumer health products.

Section 2 of this report provides a general discussion of the consumer health products industry and our estimate of its direct impact on the economy. In Section 3 the methodology used to quantify the economic footprint of the industry is discussed. Section 4 contains the results of our footprint analysis. Section 5 summarizes the findings.

2. Overview of the Consumer Health Products Industry

Consumer health products can be broadly categorized as products used by individuals to maintain their health and self-treat minor ailments. This research relies on the definition from Statistics Canada’s Retail Commodity Survey to define the industry as firms involved in selling and producing over-the-counter drugs, vitamins, herbal remedies and other health supplements. From an economic viewpoint, the industry can be disaggregated into those selling products directly to Canadians and revenues from exporting these products for consumption in other countries. This report discusses each of these revenue segments separately since their growth rates have differed significantly over the last decade.
In 2014, Canadian’s spent $5.6 billion on consumer health products. This represents 1.1 per cent of all retail spending in the country. While growth in Canadian spending on these products has slowed in recent years, the long-term trend is positive. (See Chart 1.)

![Chart 1](chart1.png)

**Chart 1**
Domestic Sales of Consumer Health Products Post Strong Growth
(percentage change)

Looking at average annual growth over the last decade, sales of consumer health products grew much faster than overall retail sales, averaging annual compound growth of 4.2 per cent per year compared to total annual retail sales growth of 3.8 per cent.

In 2014, the $5.6 billion in retail spending on consumer health products directly contributed $2.1 billion to Canada’s gross domestic product (GDP). This represents $300 million in manufacturing and $1.8 billion in wholesale and retail trade value-added output. Gross domestic product is a different concept than revenue; GDP measures value-added—the wages, salaries and profits generated within the industry—which can be roughly thought of as industry sales minus input costs. The GDP estimate in this analysis accounts for the fact that a portion of consumer health product sales are imported and, therefore, do not contribute to domestic economic growth.

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1 Detailed information on how sales revenue translates into GDP is available in Section 3.
Exports of consumer health products were estimated at $1.5 billion in 2014—almost double their 2004 value. Overall export growth in Canada struggled throughout much of last decade as the strong Canadian dollar reduced our international competitiveness. However, the consumer health products industry defied this trend with a 93 per cent increase in exports between 2004 and 2014 compared to the 27 per cent increase in total exports.² (See Chart 2.)

Chart 2

Exports of Consumer Health Products are Growing Much Faster than Total Exports (percentage change)

Sources: The Conference Board of Canada; Industry Canada Trade Data Online.

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Export performance in this industry is even more impressive when compared to growth in non-energy exports. Excluding exports from the mining, oil and gas sector and petroleum and coal product manufacturing, Canadian exports grew by just 5 per cent during the last decade. Our estimates suggest that CHP exports directly contributed $636 million to Canada’s economy in 2014, with the largest impacts occurring in manufacturing ($450 million) and wholesale trade ($140 million).

Consumers are becoming increasingly aware of the benefits of maintaining a healthy lifestyle and this has helped push up demand for consumer health products in Canada. This trend is not isolated to Canada, with exports for this industry posting very strong growth over the last decade due to a robust increase in demand and Canada’s reputation as a high-quality supplier in the natural health products industry. Overall, the industry’s combined domestic and international sales in 2014 are estimated at $7.1 billion, contributing $2.7 billion to the GDP. Of this, $1.9 billion occurred in the retail and wholesale trade sectors and $750 million in manufacturing production.

In addition to its direct impact, the consumer health products industry contributes indirect and induced impacts to the economy. For this study, The Conference Board of Canada used its proprietary national econometric forecasting model in conjunction with Statistics Canada’s input-output (IO) model to calculate the industry’s full economic footprint, including direct, indirect and induced impacts. The following section provides a detailed description of the methodology used to conduct this analysis, and the results are discussed in Section 4.

3. Methodology

The goal of this report is to estimate the total economic footprint of the consumer health products industry, defined as its direct, indirect and induced impacts. In order to estimate the economic footprint, this research uses economic models to define and describe how activity in one industry can have wider repercussions on the economy. The most obvious impact of any industry is the economic activity directly attributed to it, which is comprised of the wages of those directly employed in the industry and the profits generated. In addition to this direct impact, an industry creates demand for inputs from other industries through the course of its operations, which are referred to as indirect or supply-chain impacts. The final impact—induced impacts—occurs when employees in

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3 Agriculture and Agri-Food Canada, Opportunities and Challenges Facing the Canadian Functional Foods and Natural Health Products Sector (Ottawa: Agriculture and Agri-Food Canada, 2014).
industries that generate direct and indirect impacts spend their wages, further contributing to the economy. We describe each of these impacts in this section.

The first step in the footprint analysis was to determine the size of Canada’s consumer health products industry, which is also called its direct impact or GDP. To calculate the industry’s GDP, we used its revenues and Statistics Canada’s industry input-output model to estimate value-added production in the industry’s manufacturing and wholesale and retail trade sectors.

We obtained revenue data for the consumption of consumer health products from Statistics Canada’s Retail Commodity Survey. Export revenues for the industry are not readily available and required an estimate. We divided the data on total export revenues for the pharmaceutical and medicine manufacturing industry⁴ into consumer health products and prescribed medicines by assuming that the share of consumer health products in total drug consumption (where total drugs includes vitamins, health supplements and prescription and non-prescription medicine) was the same as the industry’s export share⁵. Combining the total consumption and export revenue provides an estimate of the industry’s overall revenue.

Using both the revenue and the Statistics Canada IO model estimates discussed above, it is possible to estimate the direct contribution of the consumer health products industry to Canada’s GDP. Using total revenues, we completed two shocks using Statistics Canada’s IO model (one for consumption and one for exports) to determine the relationship between industry revenues and GDP.⁶ The IO model contains information on the detailed linkages underpinning our economy and is able to estimate, at a very disaggregate level, how sales of a particular commodity translate into economic value-added output.⁷ Based on the estimate of direct GDP for the industry, we can also estimate its total economic footprint. A footprint analysis involves identifying the supply chain linkages in the consumer health products industry and quantifying its impacts on key economic indicators such as GDP, employment, income, and government revenues. The footprint

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⁴ Export revenues are from Industry Canada’s Trade Data Online and correspond to NAICS code 3254.

⁵ Export revenues were estimated as (consumption of consumer health products/total drug consumption)×pharmaceutical exports.

⁶ For a description of Statistics Canada’s IO model, refer to Appendix A.

⁷ Value-added or net output is the difference between total revenue and the sum of expenses on parts, materials, and services used in the production process. Summing the value-added across all industries in a region will yield the GDP in that region.
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analysis in this study evaluates the combined direct, indirect, and induced economic impacts, where:

**Direct impacts** measure the value added to the economy from the consumer health products industry that can be directly attributed to industry employees, the wages they earned, and revenues generated by firms.

**Indirect impacts** measure the value added that the “direct impact firms” generate within the economy through their demand for intermediate inputs or other support services. For example, the consumer health products industry creates demand for banking and telecommunication services.

**Induced impacts** are derived when employees of the aforementioned industries spend their wages and owners spend their profits. These purchases lead to more employment, higher wages, and increased income and tax revenues, which can be felt across a wide range of industries.

To derive the indirect and induced economic impacts associated with the consumer health products industry, the Conference Board relied on simulation results from Statistics Canada’s national IO model and the Board’s proprietary national forecasting model. We then used the results of the IO simulations to assess the impact of the industry on a broad range of economic indicators.

While the input-output estimates provide a very detailed account of the supply chain linkages, the Conference Board’s national model has the benefit of assessing what the full impacts mean for a range of economic indicators such as income and government tax revenues.\(^8\) We used the Board’s national forecasting model to estimate the total economic footprint of the consumer health products industry on the Canadian economy in 2014.

### 4. Results of the Economic Footprint Analysis

Section 2 examined the direct economic impact of the consumer health products industry. However, the direct impacts are only part of the economic story since they don’t account for the demand that the industry creates in other sectors of the economy. Economic activity linked to demand that the industry creates for supply chain inputs are referred to

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\(^8\) A description of the Conference Board’s national forecasting model is contained in Appendix B.
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as indirect impacts and are an important consideration when evaluating the role of an industry in an economy. Furthermore, additional economic benefits accrue when employees in the direct and supply chain industries spend their wages and salaries. These are referred to as induced economic impacts. Evaluating the total economic footprint of an industry involves combining the total direct, indirect, and induced impacts. In this section we expand the analysis to calculate the total economic footprint of the consumer health products industry on Canada’s economy. Through this analysis, we determine the economic multipliers that describe how GDP and employment would respond to a potential increase in sales.

Our research suggests that the economic footprint of the industry accounted for $5.8 billion in GDP in 2014. (See Table 1.)

Table 1
Economic Footprint of the Consumer Health Products Industry: Key Indicators
(2014, $ millions)

<table>
<thead>
<tr>
<th>GDP at market prices</th>
<th>5,776</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct GDP of the consumer health products industry</td>
<td>2,706</td>
</tr>
<tr>
<td>Indirect (supply chain)</td>
<td>1,587</td>
</tr>
<tr>
<td>Induced</td>
<td>1,483</td>
</tr>
<tr>
<td>Employment</td>
<td>56,878</td>
</tr>
<tr>
<td>Wages and salaries</td>
<td>2,649</td>
</tr>
<tr>
<td>Other labour income*</td>
<td>542</td>
</tr>
<tr>
<td>Corporate profits</td>
<td>848</td>
</tr>
<tr>
<td>Personal income taxes</td>
<td>518</td>
</tr>
<tr>
<td>Corporate income taxes</td>
<td>288</td>
</tr>
<tr>
<td>Sales taxes</td>
<td>606</td>
</tr>
<tr>
<td>Federal government balance (national accounts balance)</td>
<td>1,255</td>
</tr>
<tr>
<td>Provinicial government balance (national accounts balance)</td>
<td>765</td>
</tr>
</tbody>
</table>

*Includes supplementary labour income and labour income of the unincorporated sector
Sources: The Conference Board of Canada; Statistics Canada Canadian Input-Output Model.

Impacts of the consumer health products industry can be felt across a wide range of economic indicators. The economic output it creates supports a total of 56,878 jobs across the country, boosting household income (wages and other) by $3.2 billion. Businesses also benefit, with $848 million in corporate profits attributable to the economic activity that this industry sustains.
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Income earned by industry employees is a notable source of government tax revenue. In 2014, the federal and provincial governments collected $518 million in personal income taxes and $288 million in corporate taxes thanks to the economic activity supported by Canada’s consumer health products industry. These products also accounted for a total of $606 million in collected sales taxes. In addition, government balances improve beyond the increase from these three sources of tax revenue because of other taxes (e.g., non-sales taxes on products, and the social insurance contributions of industry employees) and reduced employment insurance payments. The combination of all these factors improved the federal government balance by $1.3 billion and increased the collective provincial government balances by $765 million.

A wide variety of economic sectors benefit from the impact of the consumer health products industry. (See Chart 3.)

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9 Consumer health products are subject to sales taxes in most Canadian jurisdictions, however British Columbia does not charge its provincial sales tax on over-the-counter drugs, or on vitamins and supplements. See B.C. Government Bulletin PST 207 available at: http://www.sbr.gov.bc.ca/documents_library/bulletins/pst_207.pdf
The largest impacts occur in the industries that consumer health products directly impact: retail trade, wholesale trade and manufacturing. The retail and wholesale sectors capture much of the direct consumption impact (domestic sales), while the manufacturing industry benefits from a large share of the export impact (foreign sales). In total, the economic activity generated by the consumer health products industry lifted real output by $1.2 billion in retail trade, by $760 million in wholesale trade, and by $880 million in manufacturing. The largest supply chain impacts occur in the finance, insurance and real estate industry, and the professional and technical services industry since the consumer health products sector generates notable demand for banking, leasing, legal and accounting services.

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10 These industry GDP statistics are measured in basic prices at 2007$ and reflect inflation-adjusted estimates. The most often quoted GDP statistics refer to expenditure-based GDP measured at market prices; basic prices GDP is lower than market prices GDP and is calculated as market prices minus taxes and subsidies on products.
Employment gains are distributed in a similar pattern to the GDP impacts. (See Chart 4.)

**Chart 4**

**Employment Impacts of the Consumer Health Products Industry**

*direct, indirect and induced jobs by industry*

<table>
<thead>
<tr>
<th>Industry</th>
<th>Jobs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale and retail trade</td>
<td>29,642</td>
</tr>
<tr>
<td>Other commercial services</td>
<td>11,522</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>8,352</td>
</tr>
<tr>
<td>Finance, insurance and real estate</td>
<td>2,355</td>
</tr>
<tr>
<td>Public administration</td>
<td>1,917</td>
</tr>
<tr>
<td>Transportation and communication</td>
<td>1,864</td>
</tr>
<tr>
<td>Primary Sector</td>
<td>485</td>
</tr>
<tr>
<td>Construction</td>
<td>479</td>
</tr>
<tr>
<td>Utilities</td>
<td>261</td>
</tr>
</tbody>
</table>

Sources: The Conference Board of Canada; Statistics Canada Canadian Input-Output Model.

In 2014, Canada’s consumer health products industry supported almost 30,000 jobs in the wholesale and retail trade sector plus nearly 12,000 more jobs in other commercial services (e.g., professional and technical) and an additional 8,000 jobs in manufacturing. Direct impacts accounted for slightly more than half of the total jobs created, while supply chain and induced impacts supported the remaining jobs.

Increases in GDP and direct, indirect and induced employment can be expressed as multiplier impacts, which detail the total economic response to an increase in industry demand or the total footprint relative to the direct impact. Table 2 shows the multipliers for the consumer health products sector for each of its demand segments, as well as the overall industry multiplier.
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| Table 2 |
|---|---|---|
| **Consumer Health Products Industry Multipliers** | GDP | Employment |
| **Consumption** | | |
| Impact/$1,000,000 in demand | $786,531 | 8.2 |
| Total impact/direct impact | 2.01 | 1.8 |
| **Exports** | | |
| Impact/$1,000,000 in demand | $939,296 | 7.7 |
| Total impact/direct impact | 2.14 | 2.5 |
| **Total industry** | | |
| Impact/$1,000,000 in demand | $818,696 | 8.1 |
| Total impact/direct impact | 2.04 | 1.9 |

Sources: The Conference Board of Canada; Statistics Canada Canadian Input-Output Model.

In Table 2, the first row for each segment shows the economic response to an increase in demand for consumer health products. On the consumption side, a $1 million increase in demand would generate a total GDP impact of $786,531 and support 8.2 jobs. The second row expresses the total impact as a share of the direct industry impact. The GDP impacts associated with consumption show that for every $100 in direct GDP generated by the industry, an additional $101 in GDP is created through its indirect and induced impacts. Similarly, every 100 jobs that the consumer health products industry creates support an additional 80 jobs across the country.

For the export segment, the GDP multiplier is higher relative to the consumption results while the employment multiplier is lower. Exports have a larger impact on GDP than an increase in consumer demand because some of the products purchased by Canadians are imported. Although, some products are imported through the supply chain to generate exports this is much lower than the total imports brought in to support domestic consumption. Exports have a lower impact on employment than GDP since much of the direct impact occurs in the manufacturing industry where productivity—the output produced by each worker—is higher compared to the retail and wholesale trade sector. By comparison, retail and wholesale trade accounts for most of the direct impact from the domestic consumer health products industry. Higher productivity means that fewer workers are required to produce each unit of output. On the other hand, compared to consumption, the export segment has a much larger relative supply chain impact, so the export multipliers that express the total impact (jobs) as a share of the direct impact (jobs directly created) are higher.
The total industry multipliers are a weighted average of the consumption and export results and show that every $1 million in demand for consumer health products generates a GDP impact of $818,696. Moreover, every 100 jobs created by this industry supports an additional 90 jobs.

5. Research Summary

This research examined the total economic footprint of Canada’s consumer health products industry in 2014. Over the last decade, consumption of these products has been growing faster than overall retail spending, and the industry’s exports have grown substantially faster than Canada’s overall non-energy exports despite a challenging environment caused by a significant appreciation of the Canadian dollar during that time period.

Results from our analysis show that total sales of consumer health products were valued at $7.1 billion last year. The industry is comprised of manufacturers, wholesalers and retailers that directly contributed $2.7 billion to Canadian GDP in 2014. After accounting for the entire supply chain and the impact of those employed in the industry, the total economic footprint of the industry accounted for $5.8 billion in GDP and supported close to 57,000 jobs. Income gains supported by the consumer health products industry are widely distributed throughout the economy, generating household income of $3.2 billion and corporate profits of $848 million. The industry also generated net income for the federal government in the order of $1.3 billion and provincial government net income of $765 million.
Appendix A: Input-Output Models

Input-output (IO) models are economic models that describe how goods and services flow through an economy. They have two key elements—geography and commodities—that represent particular goods or services. The IO model encompasses information about which industries produce these commodities and how they are used—either as inputs into other industries, consumed domestically, or exported. The geography element tracks where production takes place and the trade of various commodities across provincial and international boundaries.

One application of IO models is calculating the economic impacts associated with different types of economic activity. Because the model describes how supply chains work, we are able to “shock” the IO model and observe how the impact feeds through the economy. “Shocks” are inputs into the model, which can take different forms. For example, for this research, sales revenue for consumption and exports in the consumer health products industry were identified and the corresponding commodity output was increased by an amount equal to domestic sales and total exports. Through the IO model, we can trace how the increase in demand for these commodities translates into GDP and employment.

The IO model used in this analysis is produced and maintained by Statistics Canada, which annually updates the IO tables used in the model as part of the Canadian System of National Accounts (CSNA). The CSNA is a system of integrated statistical accounts with four main components: input-output accounts (national and provincial), income and expenditure accounts (national and provincial), balance of payments, and financial and wealth accounts. The IO tables cover all economic activities conducted in the market economies of each province and territory, encompassing persons, businesses, government and non-governmental (non-profit) organizations, and entities outside its jurisdiction that give rise to imports or exports (interprovincial or international).

To compile the IO accounts, Statistics Canada obtains source data every year for each province and territory from all relevant surveys and administrative sources such as tax records, professional and industry organizations, and non-government institutions. In the process of preparing statistical estimates, data from various sources are analyzed by subject-matter experts, and used to compile estimates that are consistent with all other estimates in the system and to provide a valid and coherent statistical picture of the subject matter. Consistency is a key feature of the statistics produced by the IO accounts.

As a result, Statistics Canada’s IO model is the most comprehensive description of how economic activity flows through the Canadian economy. It describes the flows for more than 700 different commodities and 300 different industries across all provinces and territories. The model solutions include both “open” results, which summarize the direct and indirect impacts of a shock, and “closed” results, which summarize the combined direct, indirect, and induced impacts. Key outputs from the model that can be used to describe the results of a shock include employment, GDP, labour income, gross output,
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and international trade. The results described here used Statistics Canada’s 2010 IO model, the most current available at the time of the analysis.

**Key Assumptions**

Although IO models can be useful tools for understanding the economic impacts associated with particular projects, it is also important to note that a number of assumptions are embedded in the results. The following section discusses some of these major assumptions.

**Fixed Production Patterns**

The tables that underlay the IO model are based on the supply chain relationship in the Canadian economy at a fixed point in time—in this particular case 2010. As such, the model results do not account for how factors such as changes in relative prices for different inputs, productivity, and technology can impact supply chains over time. As well, trade flows do not incorporate external factors, such as changes in exchange rates, the emergence of new trading partners, or changes in trade policy.

This assumption is also pertinent in the discussion of induced effects. The model assumes fixed consumption and savings patterns for consumers over time. In reality, spending and saving patterns are influenced by a variety of factors including economic circumstances and demographics. As a result, the further ahead in time you look using an IO model, the less likely it is that future economic activity will be accurately reflected.

**Lack of Supply Constraints**

Another key assumption embedded in the IO results is that there are no supply constraints on the economy. This means that the model results assume that all of the inputs needed to conduct the shock are readily available, and that any increase in production will not be competing with others for resources. In reality, if a project is of significant size it may lead to higher prices and/or wages as new production draws resources away from other activities.

This is particularly pertinent in the discussion of the induced effects. The induced effects assume that the people employed as a result of the direct and indirect effects would otherwise be unemployed, but at least some of them would likely find other employment, though their pay may be less. Thus, including the induced effects likely overstates the total economic effects; however, not including them certainly understates the total economic effects.
Appendix B: The Conference Board’s National Forecasting Model

The national forecasting model, known as the Medium-Term Forecasting Model (MTFM), is a quarterly model of the Canadian economy. The model was originally designed for forecasting and simulations over the short to medium term. More recently, the notion of potential output was incorporated in the model allowing MTFM to be used for long-term analysis.

MTFM differs from many other quarterly macroeconomic models in its emphasis on factors that are important for forecasting the medium-term prospects for the economy. These factors include a detailed consideration of population and its age structure, a disaggregated modelling of prices, employment and investment expenditures. The government sector is also treated in great detail in MTFM and reflects the most recent institutional environment.

There are about 900 endogenous variables in the model, of which nearly 400 have stochastic equations. The endogenous variables refer to many of the variables in the National Income and Expenditure Accounts as well as related indicators for productivity, wages, prices, financial markets, international capital flows and exchange rates. Over 600 of these variables form a single simultaneous block in the model, reflecting the significant interdependence of its various sectors. The most important of the 1,000 exogenous variables in the model are foreign economic indicators and variables relating to government expenditures and revenues and demographic characteristics of the population.

Of the final demand categories, government expenditures are determined exogenously. Real disposable income, population and real interest rates largely determine consumer spending on goods and services. Business investment is determined by the user cost of capital, corporate profits net of taxes, and overall economic activity. Real interest rates, income and demographic factors affect investment in residential construction. Imports are largely driven by consumer spending, investment in machinery and equipment, and relative prices. Exports are driven by relative prices and U.S. demand.

The level of detail available in MTFM’s final demand breakdown (roughly 50 categories) is key in determining production by industry through a detailed input-output block. MTFM incorporates Statistic Canada’s most recent estimates of the industrial structure of the Canadian economy (2005 is currently available). The input-output block produces an industrial breakdown of more than 60 industries.

Employment is modeled as a function of industrial output, labour productivity and wages. In turn, wages are a function of employment, inflationary expectations and lagged productivity.
In order to forecast prices, it is necessary to project potential output. In other words, it is essential to forecast the supply side. The behavioural equation for supply capacity takes the form of a Cobb-Douglas production function. Potential output depends on the factor inputs—capital, labour and productivity in which each factor input is, in turn, also determined endogenously. The labour input is a function of the natural rate of employment and the labour force. Capital stock is determined simply as the capital stock at the end of the last period plus new investment less depreciation.

Final demand prices, including consumer spending deflators, investment and exports are influenced by specific industry prices but also by the key price. The key price, represented in MTFM as the consumer price index, is driven largely by the economy's performance relative to potential: the output gap. The price block also contains a detailed bottom-up, stage-of-processing price model. In this block, raw material prices feed industry prices, which in turn feed final demand deflators and other associated prices. The small size and openness of the Canadian economy is such that many prices are determined on world markets and the prices of imported commodities feed into the price block at each of the three stages of processing.
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 (US) regarding the introduction of new products by an average of 7 years due to: (1) and a lack of regulatory incentives such as data protection; (2) administrative red tape causing delays for 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 US 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 US (see Attachment A for a list of products and their current switch status between the US 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 US, 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 the application. These additional 3 years, which do not have to be consecutive to the original 5-year protections, has been a major driver of the Rx-to-OTC switch process in the United States, by providing an incentive for manufacturers to conduct research on potential consumer uses for established prescription drugs.
- 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 US 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).

About CHP Canada

Consumer Health Products Canada (CHP Canada) is the national industry association representing manufactures of consumer health products. Many of CHP Canada’s members are global multi-national companies based in the US.

Compared to overall sales growth, Canada’s domestic and international sales of consumer health products have increased rapidly over the last decade. 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.

The industry directly employs 30,300 employees in manufacturing and the wholesale and retail trade sectors, and supports an additional 14,500 employees through its supply chain. These employees also contribute to the economy as they spend their income. Combining these three impacts provides an estimate of the total economic footprint of the consumer health products industry in Canada, which is valued at $5.8 billion in GDP and supports almost 57,000 jobs.
## ANNEX A

### 1. Switch Lag (US vs Canada):

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

Average switch lag: 10 years

### 2. Products not yet available OTC in Canada, but are OTC in US

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

Mutual Recognition Agreement for pharmaceutical good manufacturing practices between Canada and the US

(For Information only)

Summary:

- While both Canada and the US have established Mutual Recognition Agreements (MRAs) with the European Union (EU), in 2014 the Canada-US 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-US RCC provides the ideal opportunity to gain a formal commitment from the Canadian and US 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 boarders.

Background

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 US, 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.
Many of CHPA’s and CHP Canada’s and members are global multi-national companies based in the US 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 EU 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-US Regulatory Cooperation Council (RCC) Work Plan committed Health Canada and the US 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 US 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 US FDA and the EU 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 US FDA and the EU announced the MRA for drug GMP inspections.

**Current Status**

Despite the fact that OTCs are manufactured in Canada and the US to similar GMP requirements and similar protections, and despite the fact that both Canada and the US have entered into MRAs with the EU, the lack of an MRA between Canada and the US 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 US undermines the attainment of the RCC objectives to produce tangible benefits to trade between Canada and the US.

**Considerations**

**Policy Alignment:**

- Pursuing an MRA for GMP inspections between Canada and the US 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 US 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 US. It would create a shared, tangible regulatory outcomes that are business-friendly, reduce costs, and increase economic efficiency without compromising health, safety and standards.
In 2012, the US 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 US 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 US 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 products manufactured in countries with little regulatory oversight.

**Resource Implications:**

- A MRA for drug GMP inspections between Canada and the US 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, which would result in the biggest payoffs for regulators, mitigating the greatest potential risks to Canadian and US 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 EU countries that the US 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.

  - 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 domestic inspections occur every 3 years, we estimate the cost of one inspection and administrative licensing can range from $25,000-$120,000 CDN, which represent 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 if 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 that are coming from a licensed facility in the other country. The costs of retesting products can range from $150,000-$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 regular is required to show compliance of a site, 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-US 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.