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):

Ingredient	Product Category	US brands	US 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 US

Ingredient	Product Category	US brands	US OTC Approval	Status in Canada	How long have they been available OTC in the US?
ketotifen	antihistamine eye drops	Zaditor	19/10/2006	Rx	11
terbinafine	Topical antifungal	Lamasil Derm gel	24/7/2006	rx	11
orlistat	weight loss aid	alli	7/2/2007	Rx	10
lansoprazole	Acid reducer to treat frequent hearburn	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