Consumer Health Products Canada | Produits de santé consommateurs du Canada

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.

2. **Health Canada/US FDA Mutual Recognition Agreement (MRA)**

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