

September 5, 2017

Jennifer Stradtman  
Senior Director for Technical Barriers and Regulations  
Office of the United States Trade Representative  
600 17<sup>th</sup> Street NW  
Washington, DC 20036

Dear Ms. Stradtman:

The Consumer Healthcare Products Association (CHPA) congratulates USTR on a successful first round of negotiations to modernize the North American Free Trade Agreement (NAFTA). For more than 136 years, CHPA has represented the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements in the United States. CHPA members include many household name U.S. companies whose products provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. As the NAFTA negotiations proceed, we write to support wholeheartedly the inclusion of an annex on pharmaceuticals in the Technical Barriers to Trade (TBT) chapter of the new NAFTA.

Globally, the pharmaceutical sector is one of the most highly regulated sectors, and differences in regulatory regimes between countries can have significant impacts on innovation and growth. Narrowing those differences where possible will benefit consumers, health care providers, and health care product manufacturers in all three countries.

Please find below our views on what we believe should be included in a sectoral annex on pharmaceuticals in the TBT chapter of NAFTA. We thank you in advance for considering our views.

### **Overlapping Regimes**

Many very popular and well-known OTC medicines were once available only by prescription. Pain relief products, such as Aleve<sup>®</sup> and Advil<sup>®</sup>, and allergy medicines like Zyrtec<sup>®</sup> and Claritin<sup>®</sup> – to name a few – became available OTC through a regulatory process called the Rx-to-OTC switch (switch). Unfortunately, the Rx-to-OTC switch process in Canada performs poorly relative to the United States due to regulatory inconsistencies, limiting market access for U.S. manufactures of medicines and healthcare products.

In Canada, Health Canada reviews all the evidence submitted by a manufacturer and decides whether to approve a switch. Following that approval, manufacturers must then navigate through a variety of different provincial approval processes that both duplicate and reaffirm the original decision by Health Canada to approve the switch and determine the “drug scheduling,” i.e., where the product may be sold at retail – from behind the counter through a pharmacist, from the front shop of the pharmacy, or through any retail outlet.

This overlapping and conflicting approach is unique to Canada. Although Canada eventually reaches the same conclusions as in the United States on what products can be sold without a prescription, this uncertain and time-consuming process for Rx-to-OTC switch applications leads to long switch delays,

with Canada averaging seven to nine years behind the United States. That severely limits the OTC market potential in Canada for manufacturers of medicines and health care products, many of which are U.S. companies and members of CHPA.

The language of the pharmaceutical annex in the Trans-Pacific Partnership (TPP) TBT chapter could go a long way to address these issues if it is included in a modernized NAFTA. Specifically, point 6 of Annex 8-C speaks to the need to remove duplications in reviews and oversight of pharmaceuticals. We believe the language in point 6 of Annex 8-C could be strengthened further as follows (proposed additions highlighted below):

“6. If more than one agency is authorised to regulate pharmaceutical products within a territory of a party, that Party shall examine whether there is unnecessary overlap or duplication in the scope of those authorities and take reasonable measures to eliminate unnecessary overlap or duplication of any regulatory or administrative requirements resulting for pharmaceutical products.”

### **Mutual Recognition and Conformity Assessments**

The role of a Mutual Recognition Agreement (MRA) for good manufacturing practice (GMP) inspections is to encourage greater international harmonization, make more efficient use of inspection capacity, and reduce duplication. The 2012 Canada-United States Regulatory Cooperation Council (RCC) Work Plan committed the Food and Drug Administration (FDA) and Health Canada to increase mutual reliance on each other's routine surveillance of GMP inspection reports of manufacturing facilities for medicines and personal products. The goal was to avoid having to conduct duplicative inspections in each country. However, in the 2014 RCC Work Plan, FDA and Health Canada backed away significantly from this commitment and instead decided simply to continue to engage in existing multi-lateral fora on drug GMP inspections.

Despite the fact that OTCs are manufactured in both the United States and Canada to similar GMP requirements and with similar protections, the lack of an MRA between the United States and Canada means that both regulators need to inspect the same facility making products destined for each country. Not only are facilities being inspected twice, but when products cross the border, the same confirmatory testing needs to be repeated. This adds costs, discourages trade, and creates delays for consumers to access new products.

Article 8.6 (Conformity Assessment) of the annex in the TPP TBT chapter could address this issue regarding the retesting of products if point 6 of the Article was further articulated in a modernized NAFTA to include the following (proposed additions highlighted below):

“6. Nothing in paragraphs 1, 2 and 5 precludes a Party from verifying the results of conformity assessment procedures undertaken by conformity assessment bodies located outside its territory. However, Parties should take reasonable steps to eliminate all duplication of conformity testing unless justifiable for specific safety-related reasons.”

In addition to this change, inclusion of a statement on regulatory coherence in point 17 of the current TPP pharmaceutical annex could reinforce the need for the NAFTA countries to recognize equivalent inspection regimes through the use of MRAs. Currently point 17 falls short of prioritizing the use of MRAs and only speaks to “improving collaboration.” We recommend that point 17 be redrafted to



reflect the original 2012 commitment of the RCC's Joint Action Plan as follows (proposed additions highlighted below):

"17. The Parties shall seek to enhance collaboration on enforcement and compliance by increasing mutual reliance on each other's routine surveillance good manufacturing practices (GMP) inspection reports of manufacturing facilities for drugs and personal products, rather than having to conduct unnecessarily duplicative inspections in the other country."

### **Ingredient-Based Switch**

Canada's current system for switching prescription medicines 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 under the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade, Health Canada must notify the WTO and its member countries and delay the finalization of the switch for at least six 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, including the United States, where switches are product based, affecting only one manufacturer, and therefore do not require WTO notification.

This six-month delay in Canada, combined with the delays associated with drug scheduling as discussed earlier and the shorter approval time for second entry products, means that competing products often hit store shelves in Canada before the innovator's product has had time to establish itself as an OTC drug. It is not unknown for competing products to be available even before the innovator's product is available.

CHPA recommends an addition to the pharmaceutical annex to require each NAFTA country to review its administrative process with the goal of working toward harmonization and reduction of technical barriers as follows:

"19. Each Party shall review its approval processes and eliminate any unnecessary administrative barriers that cause delays in market authorisation."

### **Data Protection**

For the pharmaceutical industry, the costs for researching and developing products are quite substantial compared to most other industries. Moreover, the pharmaceuticals market is one of the most highly regulated around the world. As such, global companies prioritize new product development in countries where innovative products are most likely to succeed, where regulatory barriers to that success are minimized, and where innovation incentives are present.

In the case of OTC medicines and natural health products, manufacturers 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.

In Canada, the Rx-to-OTC switch often occurs a decade or more after they happen in the United States due to certain technical barriers. In particular, Canada's lack of data protection for such switches, when combined with the regulatory delays due to the overlapping drug scheduling rules and the ingredient-based switching described above, dramatically reduces the chances of a successful OTC launch. Thus, even though Division 8 of Canada's Food and Drug Regulations generally establishes a period of 8 continuous years of data protection for "innovative drugs" (new chemical entities), evidence to support new uses for existing drugs such as that required for Rx-to-OTC switches does not benefit from this data protection.

While data protection is generally covered under intellectual property rights provisions in international agreements such as the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (Article 39) and NAFTA (Article 1711), such provisions are obsolete and do not include protection for data generated for Rx-to-OTC switches. In the meantime, other laws and agreements have evolved. For example:

- In the United States, the Hatch/Waxman Act establishes a period of 5 years of market exclusivity for new chemical entities, and, separately a 3-year period of market exclusivity for new claims on existing products where new clinical data was essential for the approval the application. This additional 3 years, which do not have to be concurrent or consecutive to the original 5-year protections, has been a major driver of the Rx-to-OTC switch process here 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, separately, a 1 year of market exclusivity is provided for new clinical data to support new claims on existing products.
- Chapter 18 of the TPP text also recognized the importance of expanding data protection 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. However, Canada alone was given an option to "opt out" of this provision of the TPP.

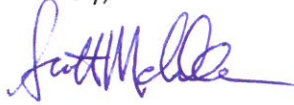
Moreover, such data protection is actually a misalignment of protections for consumer-product innovation, and as such is more a technical barrier to trade than an IP issue. This misalignment has created a chilling effect on incentives for U.S. manufacturers to export to Canada for fear that a launch in Canada will mean that they are immediately at a comparative disadvantage with local generic manufacturers. Therefore, we recommend providing the following additional provision in the pharmaceutical annex:

**"20. The Parties shall seek to align data protection measures with respect to clinical information submitted to secure non-prescription marketing approval of a previously approved prescription pharmaceutical product."**

## Conclusion

CHPA very much appreciates the opportunity to provide these comments on the proposed pharmaceutical annex for NAFTA. Should you have any questions, we would be happy to provide any clarifications or further information regarding our recommendations.

Sincerely,



Scott Melville  
President and CEO

cc: Kent Shigetomi, Director for Technical Barriers and Regulations, USTR  
Daniel Watson, Deputy Assistant, USTR for Western Hemisphere  
Elizabeth L. Kendall, Director for Intellectual Property, USTR