July 25, 2019

The Hon. Ginette Petitpas Taylor Minister of Health 70 Columbine Driveway Ottawa, Ontario K1A 0K9

Dear Minister Petitpas Taylor,

We are writing to express concern regarding the growth in legislation in the United States that permits the importation of Health Canada-approved medicines for U.S. patients. Legislation that allows the importation of medicines from Canada is popular among U.S. federal and state legislators as well as American citizens. Despite public education campaigns and statements from former and current U.S. regulatory officials to disavow importation as a strategy to reduce pharmaceutical prices, the interest in legislation has not diminished. Furthermore, U.S. President Donald Trump recently asked U.S. Health and Human Services Secretary to cooperate with Florida Governor Ron DeSantis, as the state looks to implement a new law permitting drug importation to Florida from Canada.

As a result, we request that Health Canada provide clarity and assurances to Canadians that U.S. legislation will not inadvertently disrupt Canada's pharmaceutical supply and negatively impact patient care through greater drug shortages.

Background

Over the past year, more than 27 different bills have been introduced in the U.S. Congress and state legislatures¹. The access point for Canadian medicines varies, depending on the legislation; some bills purport to allow American consumers to buy Health Canada approved medicines through 'authorized' wholesalers and Canadian online pharmacies, while others focus on personal importation from Canadian pharmacies.

Both federal and state policymakers have looked to importation as one solution to address high prescription drug prices in the United States. According to a February 2019 Henry J. Kaiser Family Foundation <u>poll</u>², eight in ten Americans support policies to buy drugs imported from 'licensed Canadian pharmacies.' In turn, elected officials, including those running for higher office, have made Canadian drug importation central to their drug pricing strategy. Some signatories to this letter have participated in educational discussions with U.S. elected officials and committees over the past year and have seen the enthusiastic support for these measures amongst US lawmakers.

Concerns

While we recognize the priority that American governments have placed on reducing the costs of prescription medicines in the U.S., we are concerned that the legal and policy frameworks that they have adopted may not address the root cause of their domestic concerns and will likely result in increased drug shortages in Canada.

The Canadian medicine supply is not sufficient to support both Canadian and U.S. consumers. Canada is allocated certain quantities of pharmaceuticals, based on estimated national requirements, by manufacturers with global supply chains. The Canadian industry, health system, and governments do not have the capacity to address the

¹ <u>https://nashp.org/rx-legislative-tracker-2019/</u>

² https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

potential increased demand that could come from a direct supply relationship between Canada pharmacy and U.S. states. The supply simply does not and will not exist within Canada to meet such demands.

In the past several years, drug shortages have become an increasingly serious concern in the Canadian health care system. As you know, Canada's pharmaceutical supply system is designed and carefully managed to serve its population of approximately 36 million and is subject to national price negotiation and regulation. Drug shortages present a challenge to Canada's health system, and jurisdictions around the world.³ A recent report published by C.D. Howe Institute found 250 drugs shortages per month in 2017⁴. According to one of the researchers behind the C.D. Howe report, Canada routinely experiences a shortage of 700 to 1000 medicines at any given time⁵. Should the U.S. proceed with any of the various importation schemes, Canadian supply will quickly be at risk of significant depletion and the ability of Canadian patients to access needed medication will no longer be a guarantee.

Hospital and community pharmacies in Canada are resourced to serve the Canadian public. They are not equipped to support to the needs of a country 10 times its size without creating important access or quality issues.

Sending consumers online to look for Health Canada-approved medicines will fuel the growth of illegal online pharmacies and result in far too many patients receiving unapproved, substandard and counterfeit drugs from unknown foreign sources, posing a serious risk to patient safety. Passing a law that encourages U.S. consumers to look for Canadian online pharmacies will create a false sense of security for patients that online pharmacies are all subject to oversight by Canadian regulators. In reality, what is likely to occur is a proliferation of illegal sites misrepresenting themselves as licensed Canadian pharmacies and exacerbating a situation that is already dangerous and threatening patient safety on both sides of the border. The National Association of Boards of Pharmacy (in the U.S.) currently estimates that roughly 35,000 active online drug sellers are operating, 96% of which operate illegally outside of Canada's borders, with 600 new illegal pharmacy sites launching every month. Canadian law enforcement cannot protect patients from illegal foreign actors who blatantly disregard both Canadian and U.S. laws, and operate anonymously or hide offshore.

Patients receiving medication through sources outside the legitimate pharmaceutical supply chain are subject to additional risks, such as: different medication brand names between Canada and the U.S.; different appearance in shape and color between countries. Such differences introduce a patient risk, through inadvertent use of the wrong medication.

In addition, regulations and enforcement are not in place to ensure the many factors attributed to proper handling of medications through the supply chain, such as temperature control, leading to destroyed, ineffective, or contaminated medications; or to the security and integrity of controlled drugs thereby contributing to drug diversion.

For these reasons, we are deeply concerned by the implications of any legislation in the U.S. Congress and state legislatures that would allow for the draining of Canada's medicine supply to the United States. We respectfully request that Health Canada intervene where necessary to ensure continuity in the Canadian drug supply. We also believe Health Canada should provide clarity to Canadians regarding the implications of these U.S. laws on the Canadian drug supply. This could include the scope of laws and regulations currently in place to protect the Canadian drug supply from leaving our borders, and necessary measures that could be taken to address any current gaps in Canadian statute.

³ <u>www.drugshortagescanada.ca</u>

⁴ https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/Commentary_515.pdf

⁵ https://www.cbc.ca/news/health/second-opinion-drug-shortages180908-1.4815355

A copy of this letter will be directly sent to the attention of Abby Hoffman, Assistant Deputy Minister, Strategic Policy, Health Canada.

Sincerely,

Alliance for Safe Online Pharmacies Canada Joelle Walker, Chair

Best Medicines Coalition John Adams, Chair & Paulette Eddy, Executive Director

Canadian Patient Safety Institute Chris Power, Chief Executive Officer

Canadian Medical Association F. Gigi Osler, BScMed, MD, FRCSC, President

Canadian Nurses Association Mike Villeneuve, Chief Executive Officer

Canadian Organization for Rare Disorders Durhane Wong-Rieger, President and Chief Executive Officer

Canadian Pharmacists Association Glen Doucet, Chief Executive Officer

Canadian Society of Hospital Pharmacists *Douglas Doucette, President*

Diabetes Canada Seema Negpal, Vice President, Science and Policy

HealthcareCAN Paul-Émile Clautier, President and Chief Executive Officer

Health Charities Coalition of Canada Connie Côté, Chief Executive Officer

McKesson Canada Anthony Leong, Vice President, Government Affairs

Neighbourhood Pharmacy Association of Canada Sandra Hanna, Vice President, Pharmacy Affairs

OnPharm-United Sherif Guorgui, co-CEO/Chief Strategy and Stakeholder Relations Officer

Shoppers Drug Mart/Loblaw Companies Limited Ashesh Desai, Executive Vice President, Pharmacy CC:

Abby Hoffman, Assistant Deputy Minister, Health Canada Supriya Sharma, Chief Medical Advisor, Health Canada Stefania Trombetti, Assistant Deputy Minister (Acting), Health Canada Chrystia Freeland, Minister of Foreign Affairs Rick Theis, Prime Minister's Office