

Policy Position – U.S. Importation of Prescription Medicines

CAPDM is the national trade association for the pharmaceutical distributors that supply pharmacies and hospitals with over 95% of medicines consumed in Canada. Together with their trading partners, the domestic pharmaceutical supply chain system is the result of steadfast stakeholder collaboration, national price negotiations, and regulatory oversight, designed to ensure safe, secure, and timely access to high quality healthcare products for all Canadians.

CAPDM opposes the exportation of pharmaceuticals intended for Canadians, whether domestically manufactured or imported. Canada already experiences significant drug shortages due to several factors, including economic and regulatory. Allowing the U.S. or any other market to draw from Canada’s drug supply will increase disruption to ready and equitable drug access. As such, we oppose any policy initiative that jeopardizes the stability of medications intended for Canadians, exacerbates already serious drug shortages, or undermines the competitiveness and attractiveness of the Canadian market.

While the U.S. Food and Drug Administration’s (FDA) decision to allow the importation of drugs from Canada is concerning on the surface, Canada has in place regulations that block bulk drug exports if such would cause or worsen a domestic shortage, and the Government of Canada is prepared to take all necessary measures to protect the Canadian drug supply. We strongly support and encourage the Government’s proactive surveillance in concert with all industry stakeholders and regular regulatory review to close any existing and potential loopholes. Any changes to legislation or regulation by the Government should guard business efficiency, without the introduction of new inefficiencies to the pharmaceutical supply chain.

CAPDM remains committed to working collaboratively with Health Canada and other stakeholders on both sides of the border to safeguard the drug supply for Canadian patients. We urge all drug establishment license (DEL) holders to comply with all Canadian regulations to protect the drug supply, and the health, of all Canadians.

ISSUE BACKGROUND

Since the early 2010’s, policymakers in the United States have pushed for drug importation to lower prescription drug costs for American patients. While it may be a good move politically to point to Canada as a solution to high prescription drug prices, economists and health care experts overwhelmingly agree that not only will importation from Canada not solve America’s domestic drug pricing crisis, but it is also wildly impractical. With a

population just ten percent of the United States', Canada's small market simply does not have enough drugs to fill America's needs.

Florida became the first state granted FDA approval to import cheaper medications from Canada on January 5, 2024, under the [Section 804 State Importation Program \(SIP\)](#). This move was predicated on the Trump administration's announcement that states could submit import proposals to the FDA for approval, a decision President Joe Biden allowed to continue. Several other states have passed laws that would allow them to create state drug importation programs and are in various stages of seeking FDA approval.

United States FDA approval for such schemes is ineffective without Health Canada licensure for exportation. Measures to protect against drug shortages were introduced by Health Canada through the *Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply)*, made on November 27, 2020. These measures were made permanent in the *Food and Drugs Regulations* in September 2021.

ABOUT CAPDM

CAPDM is the national trade association for the pharmaceutical distributors that supply pharmacies and hospitals with over 95% of medicines consumed in Canada. Pharmaceutical distributors ensure the safe, secure, and timely access of prescription and over-the-counter medications to over 11,500 hospitals and pharmacies, allowing vital medications to reach the great majority of our nation's communities on a next-day basis. With their trading partners, pharmaceutical distributors form the efficient, accurate, and reliable supply chain that ensures physical access to medicines for all Canadians.

RESOURCES

- [Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada](#)
- [Drug Shortages in Canada](#)
- [Health Canada's Food & Drug Regulations: Shortages of Drugs and Interruption and Discontinuation of Sale of Drugs](#)
- [Statement from Health Canada on FDA decision on Florida bulk drug importation plan](#) (January 8, 2024)
- [Readout from Minister of Health's discussions with U.S. Officials on Bulk Importation of Drugs](#) (January 16, 2024)