

March 14, 2024

Office of the Minister of Health
Health Canada
Address Locator 0900C2
Ottawa, Ontario
K1A 0K9

Sent via email: hcmminister.ministresc@hc-sc.gc.ca

Dear Minister Mark Holland,

We are writing to express concern regarding the Food and Drug Administration (FDA)'s authorization of the State of Florida's application to import medicines from Canada. The list of medicines for importation under Section 804 Importation Program (SIP) includes those for the treatment of HIV/AIDS, diabetes, hepatitis C, mental illness, and other conditions. At this time, twenty U.S. states have introduced or passed laws allowing the creation of state drug importation programs and are in various stages of seeking FDA approval. Particularly when Canada faces shortages of medicines, including several chemotherapy treatments and treatments for syphilis, exportation to Florida and potentially other states could intensify this issue.

We appreciate your ongoing attention to Canada's drug shortage challenges. We share your disappointment with the FDA decision and acknowledge regulations already in place to prevent shortages resulting from U.S. importation. At the same time, now that the FDA has approved the Florida plan, it is necessary to assess potential gaps existing in Canada's regulatory response to state importation plans to ensure exportation does not cause or worsen a drug shortage in Canada.

We ask you to take this opportunity to review Health Canada's current regulations and tools that address drug shortages to identify risks to Canada's drug supply in response to the FDA's approval of Florida's plan and future approvals of other U.S. state proposals.

Patient care in Canada relies upon access to drugs. As Health Canada identifies appropriate programs and policies that improve access, such as a national pharmacare program and policies to strengthen Canada's supply chain, a holistic view must be taken. Disruptions to the supply of drugs can have critical implications for patient care and add additional stress to Canada's healthcare system. As Health Canada adopts tools to protect and strengthen drug supply chains, all factors that threaten the supply chain should be considered, including importation programs.

Additionally, any drug shortage has potentially critical implications for patient care. To minimize drug shortages, Health Canada could consider adding drugs to regulations that reflect vulnerable and critical drug lists currently in development, as well as a description and process regarding when and who decides a drug is no longer in short supply. We also recommend that Health Canada prohibit medications in short supply from being sold "per prescription" to non-Canadians residing in other countries.

Now is a time to examine other loopholes that contribute to the draining of Canada's drug supply to the United States, namely unlicensed internet sellers of prescription medications that facilitate the sale of drugs approved by Health Canada and other jurisdictions to consumers in the United States.

We request your attention to these gaps to ensure U.S. consumers are not benefitting from importation programs at the expense of Canadians and Canada's drug supply.

Sincerely,

Alliance for Safe Online Pharmacies Canada
Best Medicines Coalition
Canadian Association for Pharmacy Distribution Management
Canadian Medical Association
Canadian Pharmacists Association
Canadian Society for Hospital System Pharmacists
CATIE
Diabetes Canada
Health Charities Coalition of Canada
McKesson Canada
Neighbourhood Pharmacy Association of Canada
OnPharm-United