



March 9, 2020

Comments on Notice of Proposed Rulemaking: Importation of Prescription Drugs
Docket No. FDA-2019-N5711

Introduction:

The Best Medicines Coalition (BMC) is a Canadian alliance of 27 patient organizations, together representing millions of patients, with a shared goal of equitable, consistent and timely access for all Canadians to safe and effective medicines that improve patient outcomes. Areas of interest include drug approval, assessment and reimbursement along with patient safety and supply concerns. Our Coalition strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically related to pharmaceutical care.

As part of our efforts on behalf of Canadian patients, we welcome this opportunity to comment on the Food and Drug Agency's proposed amendment to its regulations to implement section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h) to allow importation of certain prescription drugs shipped from Canada.

Core position:

Bulk importation is not viable and would put patients in Canada and the United States at risk. High drug pricing in the United States is a made-in-America issue that needs made-in-America solutions.

Canada is a long-standing neighbour, friend and ally of the United States and our two countries have a respectful shared history of collaboration. Canadians sympathize with current challenges and the need for viable solutions to address health system challenges, such as drug prices which impact the ability of many Americans to benefit from necessary medications.

However, we strongly oppose proposals to facilitate bulk importation of medicines which are intended for Canadians. It is our position that such proposals, if implemented, would put the health and wellbeing of Canadian patients at serious risk while not achieving the intended goals of providing a workable solution to prescription drug affordability issues in the United States. Ultimately, if executed, bulk importation proposals would have a negative impact on the health and safety of patients in both Canada and the United States and must be abandoned.

Sourcing drug supplies from Canada is simply not a viable option for the United States. With its small population of 38 million, Canada lacks sufficient drug supply to serve the needs of those in another country, especially one as large as the United States. Canadian patients already face ongoing critical drug shortages, a situation which would surely be exacerbated by bulk importation. Furthermore, with limited manufacturing capacity for finished drugs and extremely limited capacity to make pharmaceutical ingredients, Canada does not have the ability to expand production to meet increased demand. These issues are discussed briefly below for your consideration.

.../2

Population: Limited Canadian drug supply

With just under 38 million people, Canada is extremely small in comparison to the United States with its population of approximately 331 million. Considering that global pharmaceutical manufacturers allocate Canada quantities of prescription drugs based on population and estimated requirements, there is no capacity for bulk, commercial or wholesale quantities to be sourced for the needs of patients in another country. According to one study cited by the Canadian government, our supply would run out in only 16 weeks (118 days) if just 40 per cent of United States prescriptions were filled from drugs intended for Canada. For example, more prescriptions are dispensed in the state of Florida each year than in all of Canada. Clearly, turning to the Canadian market as a source for lower priced drugs would have an exceedingly limited and short-term benefit leaving American patients with disrupted care and without options within weeks while also causing Canadian patients harm.

Existing Shortages: Canadians face ongoing drug supply challenges

Canada currently has ongoing drug shortages which are critical without the added pressure of bulk importation of medicines meant for Canadians. These Canadian drug shortages are complicated and have proven difficult to address, putting the health of our patients at great risk as some are forced to forgo treatment or turn to medicines which are not entirely appropriate for their needs. Currently, there are more than 2,000 drugs in short or no supply as reported by Health Canada, our national regulatory agency. To provide context, that is 2,000 out of approximately 13,000 medicines approved for sale in Canada. Any action to import drugs from Canada to the United States in bulk will surely exacerbate this already dangerous situation.

Manufacturing: Canada unable to increase production capacity

It is important to clarify that Canada is not able to increase its drug supply to meet potential increased demand from bulk importation initiatives, as drug manufacturing capacity in Canada is extremely limited. Approximately 70 per cent of prescription drugs allocated for Canada are manufactured elsewhere and of those drugs which are produced in Canada 90 per cent of pharmaceutical ingredients are imported. With this heavy reliance on external sources, Canada does not have the capacity to expand production to meet the demands of bulk importation.

Safety: Increased threat of counterfeit drugs

We are concerned that proposals at the federal and state levels in the United States to enable loosely defined “suppliers” to import commercial quantities of drugs from/through Canada will increase opportunities for criminal elements to exploit loopholes, replacing bona fide medicines with counterfeits. There already is a problem in the United States with counterfeit drugs where some unscrupulous Internet-based “pharmacies” – some of whom pretend to be Canadian – are skirting existing rules designed to protect the safety of patients in the United States. Anything that could be used by criminal elements to introduce counterfeits into the drug supply chain is a credible threat to patients in the United States and Canada.

Summary:

Both the Canadian health care system and that of the United States face difficult challenges and policy makers in both countries seek solutions which will improve the health and well-being of its citizens. Regarding drug prices, we urge our American neighbours to seek appropriate long-term solutions.

We strongly believe the proposed rule is unworkable and will fail to achieve its stated purpose of lowering prices and reducing costs for patients thereby improving health. Furthermore, it will have serious consequences for Canadian patients including suffering and in some cases premature death.

Any further pressure on the drug supply meant for Canadians will not be tolerated and strongly contested by Canadian patients and our federal government. The Canadian government has repeatedly expressed that Canada's priority is to protect the health and safety of Canadians. We wholeheartedly support this position and the use of necessary measures including legislative, regulatory and policy levers to ensure the protection of our drug supply.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of Canadian patients, with a shared mission of equitable and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. Areas of interest include drug approval, assessment and reimbursement issues, as well as patient safety and supply concerns. The BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically related to pharmaceutical care. The BMC's standing goals are as follows:

- Drug programs which deliver high standards of equitable, consistent and timely access to medications for all Canadians.
- Drug review and post-marketing surveillance systems to address patient safety; knowledge of risks and benefits throughout drug lifecycle.
- Effective models for meaningful and equitable patient participation in drug reviews and policy development.

Through issue education and consensus development, patient-driven positions are communicated to decision makers and stakeholders. Formed in 2002 as a grassroots alliance, the BMC was registered under the Not-for-profit Corporations Act in 2012 and is governed by a Board of Directors elected from member organizations.

Best Medicines Coalition Members

