



GOVERNMENT OF CANADA COMMENTS ON THE PROPOSED RULE 'IMPORTATION OF PRESCRIPTION DRUGS' (DOCKET NO. FDA-2019-N-5711)

INTRODUCTION

The Government of Canada welcomes the opportunity to provide comments on the Food and Drug Administration Proposed Rule on 'Importation of Prescription Drugs' (Docket No. FDA-2019-N-5711), identified as Pathway 1 in the *Safe Importation Action Plan*.

Rising drug prices and growth in the number of high-cost medicines now available on the market is a challenge faced by all governments. In response, Canada has put in place a number of domestic measures to address increasing drug prices. Ensuring that Canadians have secure and affordable access to the medicines they need is a top priority of the Government of Canada.

The proposed rule would not provide an effective solution to the problem of high drug prices in the U.S. Canada's drug market is too small to meet American consumer demand for prescription drugs or have an impact on high drug prices. Implementation of the proposed rule could exacerbate drug shortages in Canada, putting the health of Canadians at risk.

Canada will employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed drugs.

CHALLENGES OF DRUG PRICING

Pharmaceutical spending is increasing worldwide

Global pharmaceutical spending has risen consistently over the past two decades. Drug spending per capita in the U.S. and Canada has more than doubled between 2000 and 2020. According to February 2020 OECD data on pharmaceutical spending, drug expenditures represent 12% of American and 17% of Canadian total health care spending. Spending on drugs is projected to continue to rise in both countries.

High drug prices limit the affordability of drugs to the population. Patients who are unable to afford their drugs might not fill prescriptions, ration their drugs, or use less effective, but cheaper treatment alternatives. These behaviours can lead to health consequences that further burden the health care system.

Governments around the world employ a number of domestic strategies to improve drug affordability and access for their populations. Some successful strategies include:

- *International price referencing* – setting prices by considering the price of a similar medicine in a defined basket of countries.



- *Internal price referencing* – setting prices by comparing the medicine's price against others in the same therapeutic class.
- *Negotiating bulk discounts* – using the government's purchasing power to achieve lower prices.
- *Competitive bidding* – such as tendering.
- *Value-based pricing* – setting prices by taking into account both the value of a new medicine to medical advancement and its cost effectiveness in comparison with existing treatments.

Canada uses a combination of strategies to manage drug prices

Canada uses a comprehensive approach to manage drug pricing and improve the affordability of prescription drugs. The Patented Medicine Prices Review Board (PMPRB) protects Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. Under the PMPRB's current regulatory framework, the price of a patented medicine sold in Canada is assessed against the price of the same medicine sold in other countries, or the Canadian price of similar medicines in the same therapeutic class, to determine the medicine's non-excessive price ceiling.

Additionally, the pan-Canadian Pharmaceutical Alliance (pCPA) combines the collective buying power of federal, provincial and territorial governments to negotiate lower prices on brand name drugs and set price limits for generic drugs for Canada's public drug plans. As of April 1, 2019, the pCPA was estimated to have saved approximately \$2.3 billion Canadian dollars annually for public drug plans, an amount equivalent to approximately 15% of total annual public drug plan spending in Canada.

Provincial and territorial governments can also control the prices of medicines reimbursed in their jurisdictions through other statutory, legal, or policy tools, such as restricting price increases.

IMPACT OF THE PROPOSED RULE ON CANADA

The implementation of the proposed rule could adversely affect the health of Canadians. The U.S. importation of prescription drugs intended for use by Canadians will cause pressure on the Canadian drug supply, exacerbating drug shortages and limiting access to needed medicines in Canada. Canada has seen a high volume of drug shortages, with 10-15% of Canadian drugs in shortage at any time in the past three years. Any increase in the occurrence and/or severity of drug shortages will have negative health impacts for Canadians.



The Canadian drug market and manufacturing capacity are too small to meet the demands of both Canadian and American consumers for prescription drugs. In 2017, Canada accounted for only 2% of global drug sales, compared to 44% in the U.S. In addition, Canada imports 68% of its drugs in their final dosage form.

Ensuring that Canadians have access to the prescription drugs they need is, and will continue to be a top priority for the Government of Canada. Canada will employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed prescription drugs.

CONCLUSION

Canada opposes the proposed rule, identified as Pathway 1 in the *Safe Importation Action Plan*, as it is not an effective approach to reduce drug prices in the U.S. and could exacerbate drug shortages in Canada, putting the health of Canadians at risk.

There are other domestic measures that would be more effective for the U.S to achieve its objective. Canadian officials would be pleased to meet with U.S. counterparts to share information on Canada's approach to ensuring that Canadians have access to the safe and affordable drugs they need.

