



Health Santé
Canada Canada

Regulatory Operations and Enforcement
Branch
Health Product Compliance Directorate
Jeanne Mance Building
May 20, 2020 200 Eglantine Driveway,
Tunney's Pasture
Address Locator # 1913B
Ottawa, Ontario
K1A 0K9

July 8, 2020

Jacalyn Duffin et al
duffinj@queensu.ca

20-004526-984

Dear Dr. Duffin:

Thank you for your correspondence dated March 13, 2020, regarding shortages of medications in Canada. Your letter was forwarded to the Regulatory Operations and Enforcement Branch, Health Product Compliance Directorate (HPCD) for reply. HPCD is responsible for compliance and enforcement activities related to health products in Canada and is Health Canada's focal point on issues related to drug shortages.

I value and understand the concerns you have regarding shortages of medications in Canada, especially in light of COVID-19. I sincerely apologize for the delay in responding. The spring and early summer has been a very busy time for us in HPCD and as a result there have been some unfortunate delays in responding to incoming correspondence.

Health Canada is aware of the serious impact supply disruptions of important medications can have on patients and recognizes the importance of timely communication of drug shortages to all stakeholders, including patients and their healthcare professionals. As you are aware, companies are required to report all drug shortages and discontinuances on www.drugshortagescanada.ca within specified timeframes. Timely notification and communication is an essential part of managing drug shortages, and the website facilitates this by making information available to the public. Canadians encouraged to contact Health Canada at hc.drug.shortages-penurie.de.medicament.sc@canada.ca, [should they become aware of any drug shortage or discontinuation that is not reported.](#)

Since the outbreak of COVID-19, Health Canada has been working in collaboration with its global regulatory partners, companies, provinces and territories, health care professionals, and associations, to share information and identify measures to mitigate the impact of the outbreak on patients. These measures have included exploring access to international supply and facilitating efforts by companies, whenever possible and appropriate, to make additional Canadian supply available as soon as possible.

Health Canada also convenes the Tier Assignment Committee to review drug shortage reports and to determine the level of impact a shortage may have on Canadians. The Tier Assignment Committee includes representation from across the health care system. When the Committee agrees a shortage meets the definition of a Tier 3 shortage, defined as a shortage with the

.../2



-2-

greatest potential impact on Canada's drug supply and health care system, the drug is added to the list of Tier 3 shortages found here: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/tier-3-shortages.html>. Once a drug is listed on the Tier 3 shortages list, importers may submit proposals to Health Canada to add a product to the list of designated drugs for exceptional import and sale in Canada under the recent [Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19](#).

Health Canada also co-chairs the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC), which brings key stakeholder groups together and plays a lead role in advancing tools to address drug shortages. More information regarding drug shortages and Health Canada's role in addressing them can be found here: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html>.

Addressing the complex issue of drug shortages is a multi-stakeholder responsibility requiring collaborative action from provinces and territories, manufacturers, distributors, practitioners, and the federal government. While Health Canada is responsible for regulating the safety, efficacy and quality of drugs in Canada, it does not have oversight over business decisions made by manufacturers related to the supply of a particular drug.

With the above in mind however, please be assured that Health Canada remains committed to doing its part to help ensure Canadians have access to the medications they need. When critical national drug shortages occur, Health Canada takes action as necessary and in collaboration with the provinces and territories. Health Canada also works with stakeholders across the drug supply chain to determine the details and status of a shortage, to coordinate information sharing between parties, and to identify mitigation strategies, which may include regulatory measures to accelerate resupply, if possible.

More information regarding drug shortages and Health Canada's role in addressing them can be found here: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html>.

Sincerely,

Linsey Hollett
A/Director General