



Association of Compounding
Pharmacists of Canada
Association des pharmaciens
préparateurs du Canada

November 22, 2018

Hon. Ginette Petitpas-Taylor
Minister of Health
Office of the Minister
Brooke Claxton Building
16th floor
70 Colombine Driveway
Ottawa, Ontario
K1A 0K9

Dear Minister:

We are writing to you on an issue of national importance and safety for patients requiring access to pharmaceutical medication in Canada. As you may be aware, the *Association of Compounding Pharmacists of Canada* (ACPC) www.acpcrx.org is a voluntary, Canadian organization composed of pharmacists who have pursued specialty compounding training. These skilled pharmacists have the requisite skills and expertise to prepare both simple and complex compounded preparations that are reproducible and consistent with each prescription order customized to meet patient needs. Our expertise also includes investment in specialized equipment not normally required to achieve fundamental pharmacy accreditation.

ACPC is concerned about the situation in Canada that places the safety of the public at risk as a direct result of the shortage of prescription drugs. Notwithstanding the issues facing Canada in the summer with the shortage of epinephrine (most especially- EpiPen whose manufacturer is Pfizer) we understand that antidepressant medications are in short supply as are other essential drugs that treat Parkinson's disease, schizophrenias, hepatitis prevention, hypertension, bowel disease and anesthetic drugs.

Minister, shortages in Canada are factors of three common issues: distribution, delays from third parties (wholesalers) and manufacturing. While the industry agrees with government regulation and has complied with government direction on GMP and drug establishment licensure (DEL), there are times when impact of drug shortages on the most vulnerable people in Canada can lead to death. Our concern as professional healthcare specialists in this sector is that patients and their families who cannot find the drugs they require because of the shortage of the singularly available product are not aware that other options exist – and we as compounding pharmacies believe we can provide assistance.

To that end, we appeal to you as Minister to engage with our Association to make Canadians aware that where patients cannot find available product(s) at their local pharmacies, they can seek alternatives at ACPC pharmacies located throughout Canada as one viable option. For example, compounding pharmacies can and do prepare compounded medications using API's (that are easily administered as an injectable, ointment or gel caps in a timely manner). Of course, compounded alternatives can be stored for prolonged periods at patients' homes or on their person. These options available at compounding pharmacies also serve to dramatically reduce the vulnerability patients are exposed to when shortages occur.



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I reference another option, Minister, and something you have already entertained when you signed an interim order to allow AuviQ from Kaleo in the United States into Canada to offset the shortage in EpiPens that frustrated Canadians requiring access to this life-saving treatment. In the same way, when shortages have occurred in the United States temporary approvals are usually granted to all Canadian made versions to cross the border. This in spite of the fact that our organization was very supportive of the Government's legislation to stop cross border re-importation in the early 2000's.

What is apparent, Minister, is that when there are issues of shortages that create problems like cancelled surgeries because of a shortage of anesthetic medications or when patients with depression face the added anxiety of not being able to access their medications – we think you can weigh in effectively. Here's how. At present there are APIs in storage and are unable to be used IN CANADA – that can be compounded to provide medications that can alleviate and, in some cases, remedy altogether shortages that cause concern for patients.

Compounding pharmacy has come a long way – and our association is on a mission to help government and regulatory decision makers. The issue of shortages for patients requiring access to life-saving medication is an urgent matter for us. To that end we would like the opportunity to meet with you and enlighten you and your Department on how compounding pharmacies can assist you in providing advisory and guidance on how you can resolve the issue of shortages. We know that patient safety is truly foremost in your mind when shortages for life-saving medications occur. We believe awareness to alternatives is needed and we could not be more persuasive in our appeal to assist you and regulatory officials at your Department - Health Canada.

Most third-party payers recognize this and have made considerable progress to accept professional compounding standards and thus protect the patient. We look forward to hearing from you and wish you well in the meantime.

Yours Truly,

Jarron Yee
President

Marc Kealey
Executive Director

C: Board of Directors ACPC
Dr. Supriya Sharma, Chief Medical Advisor, Health Canada