



May 6, 2017

Bruno Rodrigue
Director, Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Department of Health
Address Locator: 3105A
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Dear Mr Rodrigue,

Subject: Proposed *Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need)*

Further to the publication of the proposed *Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need)* in Canada Gazette, Part I on April 22, 2017, the Canadian Society of Hospital Pharmacists (CSHP) wishes to offer the following suggested changes to the draft guidance document:

- Question 3.2 – What information is included in the List?
 - Revise 3rd last bullet from “Canadian jurisdiction requesting the drug” to “Canadian jurisdiction where the drug is sold for use”
 - Rationale: It is CSHP’s understanding that the only drugs that will be listed are those for which Health Canada has confirmed the following:
 - there is no marketed equivalent in Canada;
 - there are no changes suspected to the benefit/risk profile related to the review conducted by the foreign jurisdiction.
- Paragraph 7.0 – Considerations
 - Add: “Given that the drugs on the List are exempt from the *Regulations amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)*, public health officials should encourage health professionals, patients and consumers to report safety incidents involving drugs on the List to the Canadian Medication Incident Reporting and Prevention System and should conduct analysis of these medication incident reports.”

Sincerely yours,

Myrella Roy, B.Sc.Pharm., Pharm.D., FCCP
Executive Director

cc Jennifer Kitts, Director, Policy and Strategy, HealthCareCAN
Cathy Lyder, Director, Members and Programs, CSHP
Glen Pearson, Past President and External Liaison, CSHP