Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

2019 July 19

Bureau of Policy, Science, and International Programs
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
Holland Cross, Tower B
1600 Scott St
Ottawa, Ontario
K1A 0K9

Email: HC.Policy.Bureau.Enquiries.SC@canada.ca

Re: Consultation - Draft Guidance Document for Industry and Practitioners on the Special Access Program (SAP) for Drugs

Dear Bureau of Policy, Science, and International Programs,

The Canadian Society of Hospital Pharmacists (CSHP) is pleased to respond to the consultation on the Draft Guidance for Industry and Practitioners on the Special Access Program (SAP) for Drugs.

CSHP's members and individual supporters include pharmacists, pharmacy technicians, and pharmacy students. CSHP is committed to patient care through the advancement of safe, effective medication use in hospitals and other collaborative healthcare settings.

CSHP supports the proposed amendments that would allow for a less burdensome process when requesting a drug that has already been authorized by SAP for the same medical emergency. Much of this administrative burden currently falls on hospital pharmacists.

We also support the proposed amendments that would allow SAP drugs to be shipped to community pharmacies. This would remove some administrative burden in cases where patients are coming in to the hospital solely to receive an SAP drug. We expect that this would also be well received by patients; some patients experience difficulty in accessing SAP drugs because they live in remote areas, or because their small local hospital does not have the infrastructure to manage SAP drugs.

CSHP recommends strengthening the proposed guidelines with the following changes.

- Responsibilities of practitioners
    - The guidance document should address the following.
        - the conditions under which the responsibility of a practitioner can be transferred to another practitioner: there may be

instances where a practitioner who is responsible for a SAP drug supply no longer works at the hospital and the full supply of drug has not been used, returned, or transferred to a new patient (via a Special Access Request [SAR]); and
        - the importance of the practitioner ensuring the patient's community pharmacy is aware that the patient is receiving a drug obtained through the Special Access Program and is provided via other means than the community pharmacy (such as a physician's office or a hospital pharmacy).
- Section 2.2.1(c) Shipping address
    - This section states that the shipping address is the practitioner's office or a pharmacy while section 3.1 (lines 398 and 399) states that "a drug may be shipped to hospital pharmacies, practitioner's office, a nuclear medicine department, a blood bank, or a community pharmacy." The additional information provided in 3.1 should be added to section 2.2.1.
- Section 2.5 Request from a manufacturer to pre-position a drug in Canada
    - The proposed guideline should not be silent on the topic of drug pricing. It should be clear that the price of a drug that is pre-positioned in Canada would not necessarily be comparable to that if the drug is subsequently given market authorization in Canada.
    - The guidance document should be clear on whether a controlled drug can be pre-positioned in Canada.
- Section 3.3.1. Adverse Drug Reaction Reporting.
    - The guidelines should state that the requirements to report an adverse drug reaction are different from those that are required under Vanessa's Law. For hospitals, this distinction is very important because they have 30 days to report an adverse drug reaction after it was first documented, and would report to a different area within Health Canada.
- Section 3.13 Return of unused stock
    - The section suggests the unused drugs would be either returned to the manufacturer or transferred for another patient. However, there are other situations where a drug obtained via the SAP could be expired or otherwise unusable. It is not clear if in those situations the drug should still be returned to the manufacturer.
    - The second sentence should be revised as follows to add clarity: "However, practitioners may request that unused supplies of a drug previously approved for a specific patient be transferred to a new patient by submitting a SAR and indicating the quantity to be transferred." The change is requested because if the SAR was approved without naming a patient, the transfer should not be required.

- Section 3.7.3 Drug shortages and discontinued drugs
    - Additional clarity is requested whether access to drugs that no longer have market authorization in Canada due to safety reasons (e.g., cisapride) or to certain controlled drugs (e.g., pentobarbital) would be terminated under the new program.
- Section 3.9.1 is missing.
- Forms
    - It is assumed that the forms will be updated to reflect the new draft guidance document.
    - While it is recognised that the majority of Special Access Requests are completed by physicians, the forms should use language that is inclusive of prescribers who are not physicians. For instance, Form B says the following, "This authority falls within the practice of medicine."

Thank you for the opportunity to provide comments on the draft guidance. If you have any questions about the information provided herein, please do not hesitate to contact me at clyder@cshp.pharmacy or (613)-912-4108.

Sincerely,

Director, Professional Practice

CC Douglas Doucette, President, Canadian Society of Hospital Pharmacists
Jody Ciufo, Chief Executive Officer, Canadian Society of Hospital Pharmacists