How to Run a Compassionate-Use Program in Canada

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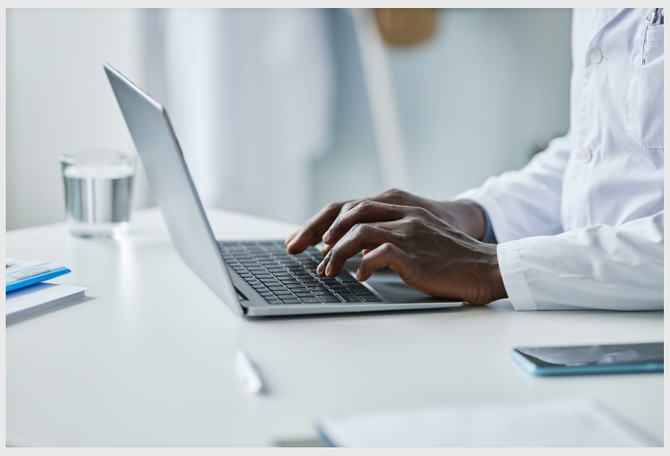
Compassionate-use Programs facilitate a vital need for the period where a clinical trial has ended until the time the investigational medicinal product becomes commercially approved. Ethically, patients who are benefiting from the medicine should continue to get access to it. The regulations on how to run a compassionate-use program vary from country to country. This article outlines how to manage continuation of patient treatment, post-clinical trial in Canada.

Terminology

Compassionate-use programs are known by multiple different names globally including Expanded Access, Early Access and Managed Access. Canada is no exception, the official name for Compassionate-use programs in Canada are 'Special Access Programs'. However, it is important to note that the term Special Access Program (SAP) does cover other programs such as named patient or unlicensed medicine. In essence, SAPs cover treatment for a patient with a serious or life-threatening condition where the medicine is not available commercially in Canada.



Application

The applicant for an SAP is not the biotech/pharma company but rather the practitioner who is looking to treat a patient. The practitioner must complete an SAP request form which must then be submitted to Health Canada for approval. The form requires information on the practitioner, drug product and patient along with the clinical rationale for using the medicine. Although not a mandatory step, RxSource recommends that the drug manufacturer submit an official statement to Health Canada confirming they are supporting the SAP. This can also provide details of the clinical trial that may have been running in Canada, the number of patients that would likely be treated and estimated length of the SAP.

If the practitioner does not have patient information, they can complete a future-use form where justification must be provided as to why patient information is not provided i.e., in the event of a medical emergency. If during the SAP, there is an adverse event or treatment changes then the practitioner should complete a follow-up form.
Typically, Health Canada will respond to SAP requests within 1 working day. All of the relevant forms can be found on the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html).

Importation

When importing into Canada it is advisable to work with an organization that are well versed in the requirements for importation and if necessary, can act as the importer of record. To successfully support an SAP, it is sometimes a requirement to hold stock at a distributor within Canada to facilitate faster distribution. Health Canada will often allow the importation of medicines for an SAP following the completion of a pre-positioning request which must be completed by the manufacturer.

To complete the importation an importer with an active drug establishment license (DEL) must be listed on the pre-positioning request. Although the product can be imported into Canada it cannot be distributed to pharmacies or clinics until the SAP request form is approved by Health Canada. The manufacturer and/or distributor must keep records of the volume of product imported, released to patients and destroyed.

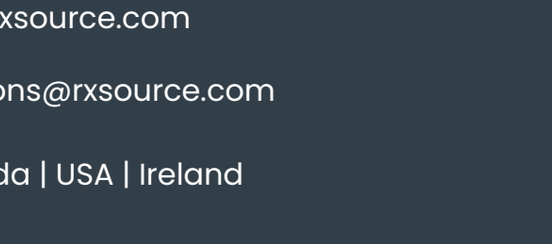
Labelling

Canada has two officially recognized languages, English and French. Consequently, any label text should contain both languages. It is sometimes the case that products which are being used on a compassionate-use basis, post-clinical trial, are already labelled as investigational medicinal products for clinical trial use only.

RxSource Clinical Services recommends that the information relevant to the clinical trial such as the protocol and clinical trial statement is removed from the label (either struck through or over labelled). Text specific to the SAP should then be added, specifically 'For Special Access Program only / Pour le programme d'accès spécial uniquement'.
Additionally, we recommend that patient specific information (such as the patient ID) is noted on the label at the point of dispatch for traceability purposes.

Distribution

Once an SAP application is approved by Health Canada the distributor is able to ship the volume of medicine stipulated on the application straight to the clinical site or pharmacy where the practitioner is based. Unfortunately, it is not possible to ship directly to a patient's home from the distributor, although the practitioner may be able to arrange a delivery from the site to the patient. It is important that the product is shipped within the required temperature range and this is monitored throughout transit.



Conclusion

In Canada, practitioner involvement is mandatory to run an SAP. They will need to complete at least one form per patient and interact with both the manufacturer and, in most cases, the distributor. This should be considered before starting an SAP. To ensure timely continuation of supply and avoid the cost of multiple importations it is advisable to use a distributor within Canada who has an active DEL. Furthermore, working with a partner that can offer demand-led labelling with patient specific information ensures traceability and compliance. RxSource Clinical Services have experience distributing for Special Access Programs in Canada, managing importation, labelling and assisting with the completion of the relevant SAP forms. Contact us to learn more on solutions@rxsource.com.

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