Notice: Clarifications Regarding Access to Restricted Drugs through the Special Access Program (SAP)

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Key messages

- Health Canada has proposed regulatory amendments that would restore potential access to restricted drugs [1], which include psychedelic drugs, through the Special Access Program (SAP). Until such time as the regulations are amended, access to these substances via the SAP remains prohibited.
- Should the regulations be amended, practitioners [2] would be able to request access to restricted drugs for their patients with a serious or life-threatening condition on a case-by-case basis when other therapies have failed and where there is sufficient evidence of safety and efficacy for the treatment of the patient's condition.
- The SAP does not have a wait list, as it is meant for emergency access.
- The proposed regulatory amendments do not signal any intent towards the decriminalization or legalization of restricted drugs, and they are not intended to create large-scale access to restricted drugs.

- Advertising of unauthorized drugs accessed through the SAP is prohibited [3].
- Health care professionals wishing to access psychedelic drugs for professional training purposes are not eligible for the SAP.
- Clinical trials remain the best option to request access to restricted drugs (or any other unapproved drugs) and to generate scientific evidence. Sponsors who are considering undertaking a clinical trial to investigate restricted drugs are encouraged to request a pre-application meeting with the Office of Clinical Trials to discuss their proposed trial and applicable regulatory requirements.

Drugs are authorized for sale in Canada once they have successfully gone through the drug review process, which includes the assessment of the safety, efficacy and quality of the drug. However, Health Canada's SAP allows practitioners to request access to drugs that are not available in Canada for the emergency treatment of patients with serious or life-threatening conditions who have exhausted other treatment options.

Due to regulatory changes made in 2013, restricted drugs cannot currently be accessed through the SAP. Although restricted drugs do not generally have authorized medical uses, the science regarding the efficacy and safety of certain restricted drugs has continued to advance. In December 2020, Health Canada published a Notice of Intent that proposed to reverse the regulatory changes made in 2013, and thereby restore potential access to restricted drugs through the SAP.

In practice, this would mean that practitioners could request access to restricted drugs through the SAP on a patient-by-patient basis on behalf of patients with serious or life-threatening conditions, in instances where other therapies have failed, are unsuitable or are not available in Canada. However, it is important to note that the proposed amendments would not guarantee that restricted drugs would be approved through the SAP. The proposed amendments would simply treat restricted drugs

like all other drugs for the purposes of the SAP. The SAP is a science-based program that only grants access to an unapproved drug where scientific evidence is available to support the potential effective and safe use of the drug for the treatment of the underlying medical condition. All requests will continue to be assessed on a case-by-case basis taking into consideration the level of evidence regarding the safety and efficacy for the proposed use, the quality of the drug, as well as the patient's condition and their clinical status.

Next steps

Should Health Canada proceed with these proposed changes, the regulatory amendments will be published in the *Canada Gazette*.

Contact us

For questions about SAP, please contact us at:

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Related links

- Notice of Intent to amend the Food and Drug Regulations and the Narcotic Control Regulations to restore potential access to restricted drugs through Health Canada's Special Access Program
- Special Access Program for drugs: Guidance document for industry and practitioners

1 Restricted drugs are controlled substances listed in the Schedule to Part J of the *Food and Drug Regulations* (FDR) (https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-189.html#docCont).

2 Section C.01.001. of the FDR (https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-94.html#h-574670) defines a practitioner as "a person who (a) is entitled under the laws of a province to treat patients with a prescription drug, and (b) is practising their profession in that province".

3 In accordance with Section C.08.002 of the FDR (https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-142.html#docCont)

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