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Regulatory Amendments Authorize Requests for Psychedelic Restricted Drugs

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01/17/2022

Emergency access to restricted drugs has been restored by recent regulatory amendments to Health Canada's Special Access Program (SAP). SAP allows health care professionals to request access to non-marketed drugs and medical devices not yet authorized for sale in Canada, on behalf of a patient. The request is intended for emergency access, meaning it must be made for treating a patient with a serious or life-threatening condition where conventional treatments either have failed, are unsuitable, or are not available in Canada.[1]

As of January 5, 2022, requests for restricted drugs, including psychedelics (e.g., MDMA, psilocybin, LSD, DMT), can now be made through SAP. The *changes* repeal the 2013 amendments to SAP, namely the revisions to the *Narcotic Control Regulations* and Parts C and J of the *Food and Drug Regulations* that prohibited the authorization of the sale or importation of a restricted drug for the purposes of SAP.[2] Through SAP, Health Canada once again has the discretion to authorize the sale of psychedelics for emergency treatments, provided the application submitted by the healthcare practitioner meets all applicable requirements.[3]

With the rise of mental health issues, this is seen as a welcomed opportunity to increase medical access to psychedelics for therapeutic purposes.[4] It also provides producers and license holders an opportunity for a new channel of trade. SAP provides an expedited route to request psychedelics for medical purposes. SAP does not have a waitlist[5] and all requests are processed within one working day of receipt.[6]

Notably, these changes do *not* guarantee that requests for access to psychedelic restricted drugs will be authorized. All SAP requests are assessed on a case-by-case basis, taking into consideration the level of evidence regarding the safety and efficacy for the proposed use, as well as the patient's condition and their clinical status.[7]

Despite the fact that there is no assurance on whether a request for psychedelics will be granted by SAP, the amendments are a welcomed change from the 2013 restrictions, presenting a new direction for medical access to the use of psychedelics. If you have questions, the regulatory team at Cassels would be happy to assist you.

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[1] Government of Canada, “Health Canada’s special access programs: Overview”, online: <Health Canada’s special access programs: Request a drug – Canada.ca> [*Special Access Program*].

[2] Regulatory Impact Analysis Statement, SOR/2021-271, *Canada Gazette Part II*, Vol. 156, No. 1, at 273 [*Canada Gazette*].

[3] *Canada Gazette*, *supra* note 3 at 274.

[4] Greg Gilman, “Health Canada Grants Special Access to Restricted Drugs for Psychedelic Therapy” (January 4, 2022) online: < https://psychedelicspotlight.com/health-canada-psychedelic-therapy-special-access-programme-amendment/ >.

[5] Government of Canada, “Notice: Clarifications Regarding Access to Restricted Drugs Through the Special Access Program (SAP)” (July 23, 2021) online: < https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/notice-clarifications-regarding-restricted-drugs-program.html >.

[6] *Special Access Program, supra* note 2.

[7] *Canada Gazette, supra* note 3 at 277.

This publication is a general summary of the law. It does not replace legal advice tailored to your specific circumstances.