

## Regulatory Amendments Authorize Requests for Psychedelic Restricted Drugs

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January 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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup>

With the rise of mental health issues, this is seen as a welcomed opportunity to increase medical access to psychedelics for therapeutic purposes.<sup>4</sup> 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<sup>5</sup> and all requests are processed within one working day of receipt.<sup>6</sup>

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.<sup>7</sup>

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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<sup>1</sup> 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*].

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

<sup>3</sup> *Canada Gazette*, *supra* note 3 at 274.

<sup>4</sup> 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/>>.

<sup>5</sup> 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>>.

<sup>6</sup> *Special Access Program*, *supra* note 2.

<sup>7</sup> *Canada Gazette*, *supra* note 3 at 277.

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