

SAP Comparison Chart

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This chart compares the Special Access Program, Section 56 and our [Proposed Regulations](#) head-to-head on a number of factors.

	Special Access Program <i>Along with clinical trials, the SAP is considered a primary pathway to access for patients in medical need. .</i>	Section 56 Exemptions <i>Section 56 exemptions for patients are now considered a secondary pathway to access - only to be pursued if the SAP is unsuitable for a patient and/or if a request for a patient has been denied.</i>	TheraPsil's Proposed 'Access to Psilocybin for Medical Purposes Regulations' <i>These regulations are not in effect. These draft regulations represent a reasonable model for patients and healthcare providers to access psilocybin for medical purposes.</i>
Source of psilocybin for patients	Health Canada approved licensed dealers or dealers who hold an import license. The Minister of Health must "issue a letter of authorization to a manufacturer to authorize the sale of an unapproved drug to the requesting practitioner, so long as the practitioner provides the required information and the request is approved, following assessment." <i>(source)</i> "Should a request for psilocybin be authorized through the SAP, the manufacturer will be issued	Patients must procure their own psilocybin from an unregulated, illicit source. Some patients choose to grow their own psilocybin mushrooms.	Patients with a valid medical document should have the ability to purchase legal, regulated psilocybin products that suit their needs. Patients should have the option to access synthetic, isolated or

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	<p>a Letter of Authorization, which permits them to legally sell the specified quantity of the drug to the requesting practitioner. If the manufacturer of the restricted drug is located in Canada, they must be a licensed dealer under the <i>Controlled Drugs and Substances Act</i> and the restricted drug must be listed on their licence. If the drug is coming from outside of Canada, the restricted drug must be imported by a licensed dealer who has the restricted drug listed on their licence and has obtained an import permit from Health Canada" (source)</p>		<p>fruiting bodies (psilocybin mushrooms) from a regulated source, (Health Canada approved licensed dealers), and also have the option to grow their own psilocybin mushrooms, should they wish.</p>
<p>Source of psilocybin for healthcare professionals for training</p>	<p>Psilocybin for training purposes is not available through the SAP. Drugs requested through the Special Access Program are only for patients.</p>	<p>Healthcare professionals enrolled in training who have successfully received an approved section 56 exemption for training purposes must access psilocybin from an unregulated and illicit source.</p>	<p>Healthcare professionals enrolled in a training program who wish to undergo experiential training should be able to access psilocybin from a Health Canada approved licensed dealer, through a medical document, similar to their patients.</p>
<p>Who applies for access?</p>	<p>Prescribing healthcare professionals (e.g doctors or nurse practitioners) request access to a drug through the Special Access Program on behalf of</p>	<p>A patient submits their own application to the exemption</p>	<p>Patients seeking access to medical psilocybin and/or</p>

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	<p>their patient. Doctors must submit the <u>request form</u> directly to the SAP by fax.</p>	<p>office via email, or an advocate does so on their behalf (e.g. family member, TheraPsil representative, doctor, etc).</p> <p>Patients supported by TheraPsil are counselled and supported in the writing, submission and advocacy regarding their exemption.</p>	<p>psilocybin therapy would book an appointment with their Doctor or Nurse Practitioner.</p> <p>The Healthcare professional (HCP) and patient would discuss psilocybin therapy and/or medical psilocybin as a potential treatment option.</p> <p>If the Healthcare professional and patient agrees this is a reasonable treatment option for the patient, the HCP would write a medical document for the patient (similar to a prescription).</p> <p>Healthcare Professionals can also write medical documents for their peers enrolled in training programs so they may access psilocybin for</p>
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			<p>experiential training purposes.</p> <p>Healthcare professionals may also refer a patient to an organization or to practitioners that can support the patient's psilocybin assisted therapy treatment.</p>
<p>Patient Eligibility Requirement</p>	<p>Health Canada stipulates that "Patients must have a serious or life-threatening condition where conventional treatments: have failed, are unsuitable or are not available in Canada." <i>(source)</i></p> <p>Health Canada further outlines that most drugs accessed through the SAP "treat patients with life threatening diseases or serious conditions such as intractable depression, epilepsy, transplant rejection, hemophilia and other blood disorders, terminal cancer, and AIDS." <i>(source)</i></p> <p>Health Canada is clear: "The Special Access Program is for emergency treatment only." <i>(source)</i></p>	<p>As of January 2022, 55 patients, supported by TheraPsil have received approved section 56 exemptions to legally use and possess psilocybin for medical purposes.</p> <p>All of these patients have met the following criteria:</p> <ul style="list-style-type: none"> • 19+ Resident of Canada, with a terminal diagnosis OR 	<p>In our proposed regulations, a patient's healthcare provider has the discretion to decide eligibility requirements for access to psilocybin.</p> <p>A healthcare professionals regulatory board might also stipulate guidelines.</p>

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	<p>Furthermore, Health Canada explains that "In determining what is a serious or life-threatening condition in a patient, several factors are considered. Such factors include but are not limited to:</p> <ul style="list-style-type: none"> • the need for hospitalization or in-patient admission/care • the risk of adverse pregnancy outcome • the risk of persistent or significant disability in the absence of treatment • the prognosis of the condition" <i>(source)</i> 	<p>in remission from a life-threatening diagnosis and/or receiving palliative care</p> <ul style="list-style-type: none"> • As a result of a past or present life-threatening diagnosis, the patient experiences psychological distress (anxiety/depression/demoralization) • The patient's emotional distress has not successfully responded to other treatments 	
<p>Who supports the application?</p>	<p>A licensed healthcare professional.</p>	<p>The patient (or their primary advocate)</p>	<p>Similar to prescriptions, only</p>

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	<p>"A healthcare professional is someone who:</p> <ul style="list-style-type: none"> • is entitled, under the laws of a province or territory, to treat patients with an unapproved prescription drug • practises in that province or territory • has prescribing privileges in the respective province" <i>(source)</i> 	<p>completes the section 56 exemption application, which includes written support from a prescribing practitioner (Physician or Nurse Practitioner).</p>	<p>physicians and nurse practitioners will be the only ones who can write a medical document for patients.</p>
<p>What is included in the application?</p>	<p>The SAP request form (A) is 8 pages long and requests: practitioner information, drug and manufacturer information, patient information, clinical rationale (including research) among other details.</p> <p><u>You can view a copy of Request Form A here.</u></p> <p>Healthcare professionals can also submit a <u>'future use' request form.</u></p>	<p>Section 56 applications supported by TheraPsil include 2 forms.</p> <p>The supporting physician completes a one page document detailing the patient's demographics, diagnosis, prognosis, symptoms, and recommended psilocybin dosing. As well as the patient's inability to access a clinical trial.</p> <p>The patient completes a two page document detailing their demographics, nature</p>	<p>The medical document in our proposed regulations must indicate the following:</p> <ul style="list-style-type: none"> • the healthcare practitioner's given name, surname, profession, business address and telephone number, the province in which the health care practitioner is authorized to practise and number

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		<p>of illness, expectations for treatment, plans for psilocybin procurement, secure storage and administration.</p>	<p>assigned by the province to that authorization</p> <ul style="list-style-type: none"> • the given name, surname and date of birth of the individual who is under the professional treatment of the health care practitioner • the address of the location at which the individual consulted with the health care practitioner • the authorized quantity of dried fruiting
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			<p>bodies, expressed in grams, that the health care practitioner authorizes for the individual</p> <ul style="list-style-type: none"> • a period of use, specified as a number of days, weeks or months, with the maximum period not exceeding one year • signed and dated by the health care practitioner who is providing it and must include a statement confirming that the information in
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			<p>the document is correct and complete</p>
<p>What happens after an application is submitted?</p>	<p>Health Canada stipulates that: "After our review, we will make a decision as follows:</p> <p>Authorization: The information meets SAP criteria. We will fax a letter of authorization to the manufacturer and send a copy to the health care professional.</p> <p>Incomplete: The SAR form is incomplete or unclear. We will contact you if there is missing information or to clarify your request.</p> <p>Cancellation: We cancelled the request because the manufacturer is unable to provide access to the drug through SAP or the drug is marketed in Canada.</p> <p>Withdrawn: The health care professional who made the request has withdrawn the application.</p> <p>Denial: The information does not meet SAP criteria. If we are considering denying the request, we may contact the health care professional to</p>	<p>Upon submission of section 56 exemption applications, patients receive an automatic reply that their application has been received. Then, patients wait for a decision response from Health Canada.</p> <p>While awaiting a response patients and their doctors are often asked follow up questions. Patients are sent an email with an exemption if/when approved outlining the conditions of the exemption. .</p>	<p>In our proposed regulations, if the patient's physician or nurse practitioner deems that the patient is suitable for psilocybin, they will provide the patient with a medical document.</p> <p>The patient can then either send their medical document to a sales license holder who will send psilocybin product to where the medical document specifies OR patient can send the medical document to Health Canada who will provide a registration certificate that will allow the patient to order starter</p>

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	<p>discuss the reasons for this. After the phone call, it is possible we may reconsider our decision.</p> <p>We will send a letter, by fax, explaining our decision to the health care professional." (source)</p>		<p>materials from a sales license holder.</p>
<p>Who receives the psilocybin? / Where the psilocybin is sent to?</p>	<p>Health Canada notes that Drugs accessed through SAP are supplied directly by manufacturers to health care professionals. For restricted drugs like psilocybin, the product can only be sent to:</p> <ul style="list-style-type: none"> • the office of the health care professional who made the request • hospital pharmacies <p>(source)</p> <p>Patients are not permitted to possess or transport the psilocybin. "which means that it has to be used in the presence of the practitioner or the health care professional to whom the practitioner has delegated this activity." (source)</p> <p>Health Canada has created a 'Class section 56 exemption' for some types of healthcare professionals, under certain conditions, who are allowed to possess, transport and administer psilocybin for patients. (source)</p>	<p>The patient who has received a section 56 exemption is the only person who legally can possess and use psilocybin.</p> <p>They must procure psilocybin themselves and be the only person in possession of the psilocybin.</p>	<p>In our proposed regulations, this is based on the medical document.</p> <p>The medical document must stipulate the location and address of who is able to receive the psilocybin and where the psilocybin must be sent. For example, this may be the physician's office, the treating therapists office, or the patient's own home.</p> <p>This stipulated address is the address the psilocybin is sent to whether the patient chooses to access psilocybin through a sales license</p>

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			<p>producer, or if the patient chooses to access starter materials via a registration certificate from Health Canada.</p>
<p>Cost of psilocybin</p>	<p>The cost of psilocybin approved through the SAP is determined by the Licensed Dealer / Manufacturer.</p> <p>Health Canada states:</p> <p>"The manufacturer determines the cost of the drug. In some cases, drugs released through SAP are free. If there's a charge, hospitals, public or private insurers or, in some cases, patients or their families will cover the cost." <i>source</i></p>	<p>Psilocybin mushrooms procured through unregulated sources are fairly inexpensive and in some cases, can be obtained for free.</p>	<p>The cost of psilocybin will be determined by the licensed dealer.</p> <p>TheraPsil will advocate for reasonably priced psilocybin so that this medicine is accessible by all in medical need.</p> <p>The cost of therapy is already cumbersome for some patients and to ensure equitable access we must work towards therapy being covered by Canada's Universal health plan, and ensure reasonable costs of regulated psilocybin products</p>

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			<p>to ensure this treatment option is accessible to all in medical need, regardless of financial ability.</p>
<p>Processing time of application</p>	<p>Health Canada states: "There are no existing service standards issued for the review of requests to the Special Access Program; however, requests are generally processed within 1–2 working days following receipt. As drugs being requested through this program are for emergency treatment purposes, Health Canada aims to respond in a timely fashion, giving priority to the most urgent requests. Requests for drugs that have not previously been authorized through the Special Access Program or for new indications generally take longer to be processed." <i>(source)</i></p>	<p>Some patients have had their section 56 exemptions approved in less than 48 hours. However some patients have waited almost 300 days for a response. There is no standard service time set out by Health Canada to respond to section 56 exemption applications.</p>	<p>Our proposed regulations remove the government, a politician or a bureaucrat from individual healthcare decisions. If patients could access this treatment option through consultation with their healthcare provider, patients could technically access this treatment option as quickly as it takes to get an appointment with their doctor, and for their licensed producer to fill their psilocybin order and for them to start therapy with their therapist (if needed).</p>

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<p>Contact Information</p>	<p>T: 613-941-2108 F: 613-941-3194 E-mail: hc.sapd-pasm.sc@canada.ca</p>	<p>hc.exemption.sc@canada.ca</p>	<p>info@therapsil.ca</p>
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