C4T Response to The Cannabis Act Legislative Review

November 21, 2022

C4T

THE CANADIAN COLLABORATIVE FOR CHILDHOOD CANNABINOID THERAPEUTICS

The Canadian Collaborative for Childhood Cannabinoid Therapeutics, formerly the Canadian Childhood Cannabinoid Clinical Trials (and also known as C4T) is an **academic research team** lead by Dr. Lauren Kelly. C4T currently has **106 members** made up of parents, youth, doctors and scientists who assembled to study medical cannabis in children. C4T is committed to advocacy for medical cannabis clinical trials, regulations to better serve pediatric medical cannabis patient safety and knowledge sharing with health care providers, patients, families and the public.

This report was prepared in response to the request from Health Canada for public engagement on *Taking stock of progress: Cannabis legalization and regulation in Canada.* This report was submitted by Zina Zaslawski, MA, Knowledge Broker, C4T and Dr. Lauren Kelly, PhD, Scientific Director, C4T on October 21, 2022.

Conflicts of interest statement: Dr. Kelly was a Scientific Advisory Board Member for the Health Products Containing Cannabis Committee at Health Canada (2020-2022) and currently sits of on the Board of Directors for the Canadian Consortium for the Investigation of Cannabinoids (CCIC). Dr. Kelly holds academic funding from the Canadian Institutes of Health Research, SickKids Foundation, Canadian Cancer Society, Mitacs, Children's Hospital Research Institute of Manitoba and Research Manitoba. Our members list and ongoing research collaborations can be found at **www.MedCannKids.ca.**

1. Minimizing Harms to Protect Canadians

Our view on the current legislative and regulatory restrictions in place to safeguard public health is that they do not adequately consider the needs of pediatric medical cannabis patients by hindering research and neglecting to consider safety guidelines or mandate pharmacovigilance. Complex institutional research licensing processes put a halt to cannabis research and all pediatric health research organizations and academic institutions (Universities). As a result of this lengthy and burdensome processes, many institutions, especially smaller ones where cannabis patients/research may be rare, will not apply for cannabis research licenses.

Cannabis products sold in Canada must meet Good Production Practices (GPP) certification, and these products are widely available, including on the medical cannabis stream. However, to be studied in clinical trials, which is how we generate safety data in complex and chronically ill children, products must obtain Good Manufacturing Practices (GMP) certification. This inconsistency makes the medical cannabis products which doctors are currently authorizing for children with epilepsy, autism, cancer and other complex health concerns, ineligible for study in clinical trials. This leaves health care providers and families without the evidence they need to safeguard their child's health. Costs are prohibitive for families accessing CBD (for reference, the approved dose of Epidiolex is up to 20mg/kg of CBD per day), leading families to underdose or seek products on the illicit (legacy) market. To create solutions that remove barriers to generating safety data, collaboration on cannabis research regulations with the **Office of Clinical Trials** at Health Canada is urgently needed.

We recognize that obtaining research licenses, generating regulatory documents (preclinical, investigator brochures etc) and obtaining GMP certification is costly and time consuming for companies. We recommend the following changes in controls:

- Health Canada to **align their production and research standards** to allow GPP-certified cannabis products to be used in clinical trials. This will require collaboration with the Office of Clinical Trials/revision of Division 5 in the Food and Drug Act or rescheduling of cannabis clinical trials that includes medical patients under the age of 18 years.
- Incentivize Canadian companies to work with researchers to develop a **formulary of several medical cannabis products** (for example high CBD, balanced, low CBD, isolates and concentrates, patches, oils, sprays, capsules) from multiple producers that meet GMP, for study in research and authorization (medical use) in children. Also, develop a pathway to a Drug Identification Number (DIN) that companies see value in, and that hospitals could then access for in-hospital prescribing.
- Establish a national cannabis-based medicine **pharmacovigilance program** and cannabis research infrastructure to ensure there are adequate population level safety data on public and medical access to cannabis products for health concerns in children.

Under the current framework, we propose that the following present the greatest risk to youth in accessing and consuming cannabis:

- The paucity of high-quality **evidence** assessing the safety, efficacy, appropriate dosing, and long-term neurodevelopmental impacts.
- Lack of **educational content that considers motivations** for youth accessing and consuming cannabis (including for medical benefit).
- Lack of **formal training in Canadian medical schools**, residency programs, and continuing professional education activities has contributed to discomfort with authorizing and dosing cannabis products.
- Lack of national **rigorous data capture** driven by youth on cannabis access, utilization patterns and impact on daily living that is required to inform policies and educational strategies with a harm reduction lens.

2. Education and Awareness to Support Informed Choices

In evaluating the extent to which the public education efforts delivered the appropriate messages and reached the appropriate audiences, including youth and young adults, we found that it is a major shortcoming. We have held 4 sessions with youth (13-19 years) and most receive little to no education about cannabis other than abstinence-based messaging. There is very limited training in harm reduction or pharmacology to understand how cannabis compounds can be used, what people are using them for, and what the risks and benefits of different cannabis products might be. Patients, for example with chronic nausea, may be prescribed drugs like nabilone. This causes stigma and confusion when they are told this is a synthetic form of THC, and the only messaging that they have heard in classrooms is that this is a dangerous substance to be avoided at all costs.

We propose that in order to continue **to close the gap between perception of risks and harms and scientific evidence, we need to generate good quality data and invest in a national cannabis pharmacovigilance and research infrastructure**. We need to enhance evidence-based education about medical cannabis to provide Canadian physicians, nurses and pharmacists the knowledge necessary to safely advise on and authorize medical cannabis products. Cannabis is also not a magical cure all and advocating for research on medical uses in complex health conditions should not be confused with advocating for cannabis exposures in children. Youth should be taught how to critically appraise messages in the media about the risks and benefits of cannabis and how to make informed decisions. Education and awareness to reduce stigma can be achieved through continuing medical education programs hosted by academic institutions or professional organizations. This includes brief virtual case-based presentations, which would help bridge the knowledge gap faced by health care providers. There are unbiased expert education programs already developed that could be made accessible to all health care providers.

3. Establishing a Safe and Responsible Supply Chain

Alternative measures, which the government could consider to further strengthen and diversify the legal market, are **affordable CBD concentrates** for administering medical cannabis orally to patients to reduce volume. This is particularly important for pediatric patients who may not tolerate large volumes of oil due to Gastrointestinal upset, palatability or G-tube degradation. Other measures the government could consider to better meet the needs of racialized, under-represented, or Indigenous communities within the cannabis licensing program are as follows:

- Children and families should be at the table to **increase representation** during discussion around cannabis licensing and impact on access to their medicines.
- The **prohibitive costs** faced by parents who desire to purchase medical cannabis for their children must be addressed. It would be ideal to have medical cannabis products placed on provincial and territorial formularies, however, in the absence of a DIN, this is unlikely to occur. As such, we encourage Health Canada and the medical community to work together to develop medical cannabis products that have a DIN available to pediatric patients.
- Cannabis products used for medical purposes and authorized by health care providers **should not be subject to the same taxation schedule as recreational cannabis** products used for recreational purposes. Medical cannabis products used by children, if authorized by licensed health care providers and purchased from Health Canada-approved legal cannabis producers, should be exempt from federal and provincial taxation.
- Until cannabinoid pharmaceuticals/medical cannabis products are available on public formularies, federal and provincial/territorial governments should **increase the amount of tax credit families** are able to claim for their child's medical cannabis. Options for non-formulary public funding, should also be considered, similar to those for necessary medical equipment and supplies for select conditions.

4. Protecting Public Safety

Participants in our qualitative studies with parents and youth report continuing to access the illicit (legacy) market products due to cost barriers with the legal market. Several additional measures for the government to consider in order to combat the illegal cannabis market are suggested below.

- Reduce prices (**remove taxes**) **for medical patients** and provide concentrated orally administered options to reduce the likelihood they obtain cheaper products outside the legal market.
- Incentivize companies to provide **compassionate pricing programs** that consider family costs related to medical care (not just income) so that patients can afford to access the legal medical market. Most compassionate cost programs are based solely on the patient's age (i.e., children under 18 years of age qualify) or on family income, and do not take into consideration the medical complexity of the child and additional healthcare costs that families incur. Considerations for compassionate pricing that incorporate income and medical expenses without an age limit would be preferable.
- Consider developing options for **non-formulary public funding,** similar to those for necessary medical equipment and supplies for select conditions where evidence has shown that benefit outweighs risk. We also encourage legal cannabis producers to offer differential costing for cannabis products used for medical versus recreational purposes.

5. Access to Cannabis for Medical Purposes

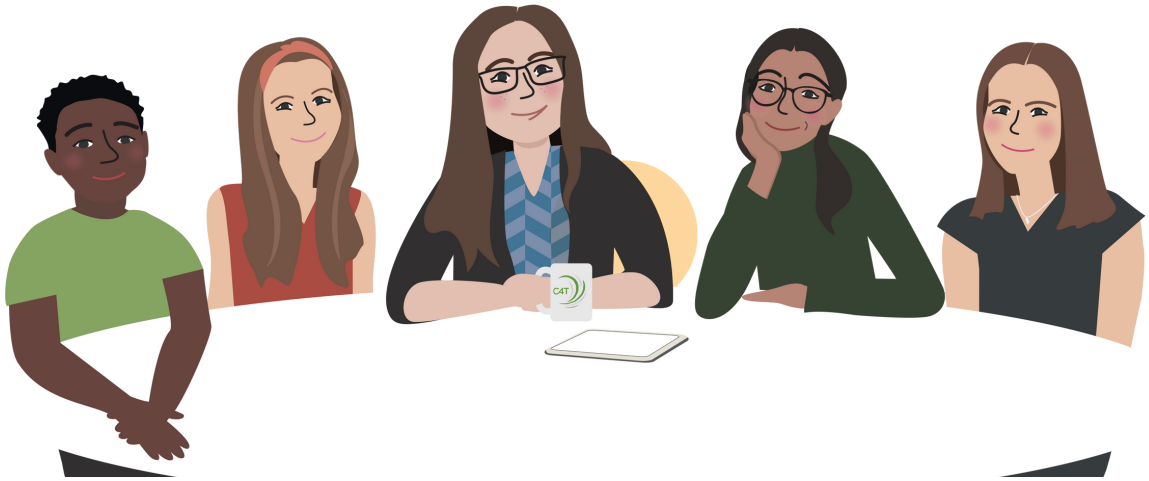
The current medical access program in cannabis has several limitations. These barriers for pediatric patients are described in an early edition of our accepted manuscript (included with permission from Pediatrics and Child Health.

- The **prohibitive cost** of medical cannabis is another major barrier for families. Products without a Health Canada DIN such as medical cannabis are not covered through Canadian provincial or territorial drug formularies. With the introduction of the Cannabis Act, medical cannabis became subject to provincial and federal taxes making it even more cost prohibitive for families.
- Parents of children with medical cannabis authorizations frequently encounter **product shortages that licensed cannabis producers are not required to report to patients** or health care providers as would be expected for other Health Canada approved drugs. Cannabis products not having a DIN is not a justifiable reason why legal cannabis producers should be able to circumvent this rule. When shortages do happen, patients, parents and health care providers should have advanced notice and **access to Certificates of Analysis** to support a transition to an alternative product.
- There is still minimal **education** available to health care providers on how to authorize medical cannabis, how to select the right product, and at what dose for which patient.

It is our position that **a distinct medical access program is necessary** to provide individuals with reasonable access to cannabis for medical purposes. **Without a medical access program, hundreds of Canadian children with complex diseases, including epilepsy, cannot access their life changing medicines.** The access program supports health care provider interactions and access to cannabis product discounts. When no support or guidance is provided, parents may prepare homemade cannabis extracts or turn to other cannabis providers, including the illicit market. Lack of medical oversight and quality-controlled production has the potential to cause harm to the child from drug—drug interactions, impurity, lack of standardization, inappropriate dosing or unintentional over-dosing and intoxication. **We support further dedication of resources to create a national pharmacy resource for health care providers to access up-to-date safety data on cannabis-based medicines.** This must be mandated federally. Leaving this to be done at a provincial level will ensure that many regions are without guidance based on competing provincial political priorities, inequities in access and historical views on cannabis-based medicines.

We recommend the following reforms to improve access to cannabis for medical purposes, particularly for pediatric patients:

- Form and manage an **unbiased national pharmacy resource** for pharmacovigilance (reporting adverse events) to support product development, and provide consultation for health care providers on cannabis-drug interactions.
- Work with industry and incentivize the development of a **formulary of GMP-certified cannabis-based medicines** for clinical trials and hospital administration
- Invest in **pan-Canadian infrastructure** to bridge the gap between patients, licensed producers and regulatory agencies to develop and test cannabis-based medicines for children.
- Mandate recreational cannabis **profits to be invested into research and education** (across all provinces, not only Quebec).
- Mandate disclosure of **Certificates of Analysis** and **product shortage notifications** (60 days) to medical cannabis patients to facilitate product switching.



Requests for additional information can be sent to **C4T.Canada@gmail.com**