Canadian Drug Policy Coalition
Coalition canadienne des politiques sur les drogues

In coalition with:

Harm Reduction Nurses Association
Association des infirmiers et infirmières en réduction des méfaits

HIV LEGAL NETWORK RÉSEAU JURIDIQUE VIH

PIVOT
equality lifts everyone

July 31, 2024

**Submission to the Canada Gazette, Part I, Volume 158, Number 22: Controlled Substances Regulations request for input**

The following submission was prepared by the Canadian Drug Policy Coalition (CDPC) on behalf of CDPC, the Harm Reduction Nurses Association, the HIV Legal Network and Pivot Legal Society.

NOTE: as the Canada Gazette portal does not allow hyperlinks, we have denoted refences with a * - all hyperlinked references are included in this PDF version of the submission and were active as of July 31, 2024.

## General Comment

For about a decade, Canada has been experiencing a severe and growing public health emergency. An average of 21 Canadians are killed each day by unregulated drug poisoning. These deaths are preventable. As a coalition of evidence-based drug policy and human rights organisations, we begin by emphasizing that the unregulated drug crisis is not being addressed with adequate urgency. The current review presents an opportunity to ensure that public health and human rights considerations are centered appropriately in the forthcoming regulations. However, the proposed Controlled Substances Regulations (CSR) do not reflect the magnitude of the crisis, nor do they provide pathways for meaningful intervention.

Fundamentally, it is our view that the stated purposes of Health Canada's proposed CSR are too narrow. However, even when evaluating the CSR according to its stated purposes, we have concerns about its underlying assumptions and its substantive content. Specifically, the CSR does not reflect sufficient awareness of the debates taking place among UN Member States about the contemporary appropriateness and efficacy of UN Drug Control Conventions. The outcomes of these debates could have significant implications for Canada's drug control regime in the future. As such, the CSR is likely to require revisions imminently if the draft CSR is not adequately revised. We elaborate on this claim and provide examples of where the UN Drug Control Conventions have been, or are being, contested, in the "Issues" section below.

Similar such debates are also being held within Canada's domestic borders. Since the mid-19$^{th}$ century, and with increasing frequency in the last two decades, multiple federal task forces and

inquiries have been convened to review Canada's regulatory framework for prohibited substances. Some of the findings and recommendations issued by expert stakeholders have already been adopted (e.g., the legalization of cannabis for non-medical use in 2018). In its current iteration, the CSR does not demonstrate the flexibility required to address existing and emerging recommendations. We will discuss this in further detail in the "Background" section.

These two sections will provide an orienting framework for our subsequent feedback and more specific recommendations.

Next, the CSR contains language throughout that is not supported by scientific evidence. Some of this language is implicitly or explicitly value-laden, stigmatizing, and considered out of date. This includes instances where a substance's legal status has been conflated with dominant myths about the causes, purposes, and outcomes of its use. A lack of neutrality throughout the CSR undermines its utility as a regulatory and legal document. We highlight where unscientific or value-laden language has been used in subsequent sections where applicable. We also offer suggestions for revisions to specific words and phrases that more accurately reflect Health Canada's role as a non-partisan regulatory agency.

Conversely, there are instances in the CSR where the expectation of a neutral policy outcome could disproportionately impact historically and contemporarily marginalized populations. We are primarily concerned with the deleterious impacts of presumed policy neutrality for Indigenous peoples, Black people*, and other racialized people living within and outside of Canada and for people living in remote and rural regions of Canada. We are also cognizant that the CSR's presumed neutrality could exacerbate inequalities for women and gender diverse people living outside and within Canada. We will focus on the impacts of the proposed CSR for Indigenous peoples, Black people, and other racialized people in the "Regulatory Development" section. We will focus on its potential impacts for people living in remote and rural regions and provide a gender-based analysis in the "Regulatory Analysis" section.

What is more, the CSR is built upon foundational assertions regarding public safety that warrant interrogation. Promoting public safety is an objective that we support wholeheartedly. However, throughout the CSR, risks to public safety have been conceptualized as resulting almost exclusively from the diversion of legal psychoactive substances into the illegal market. A narrow focus on diversion ignores the immediate risk to public safety posed by the consumption of unregulated substances. It also obscures the myriad public safety risks, local level socio-economic impacts, and the criminal-legal harms caused and amplified by criminal enforcement-based approaches to drug control, all of which are disproportionately imposed on Indigenous, racialized, socially and economically equity-denied communities, who lack legal pathways of access to regulated substances, or lawful economic opportunities within the licensing model.

It is important to note that domestic law and regulations for psychoactive substances can evolve to better protect public health and public safety based on an integrated understanding of the UN Drug Control Conventions in conjunction with international human rights standards, as observed in the implementation of the *Cannabis Act* in 2018 which introduced a regulatory system for the

cultivation, processing and sale of cannabis. The purpose of the *Cannabis Act* is centrally to protect public health and public safety, as well as provide for the licit production of cannabis to reduce illicit activities and provide controlled and accountable access to a quality-controlled supply of cannabis. This demonstrates that producing and providing access to quality-controlled substances does not necessarily contradict public health and public safety considerations, even if those substances remain scheduled in UN Drug Control Conventions.

We will provide a summary review of the literature examining correlations between current criminal enforcement-based drug policies and risks to public safety, including in the international arena, in the "Description" and "Licensed Dealers" sections. We will also offer specific suggestions for amending aspects of the CSR so that Health Canada's licensing regulations better align with best practices for promoting public safety.

Our feedback follows seven general themes:

- Inadequate assessment of public health and human rights impacts
- The evolving nature and contemporary debate on UN Drug Control Conventions
- Lack of neutrality in language
- Disproportionate harmful impacts to equity-denied groups
- Inadequate framing of public safety
- Inadequate safeguards to ensure the rigor of information relied upon in Ministerial decision making
- Lack of flexibility to meet arising needs and promising practices

**Executive Summary (20,000)**

First, the use of the word "legitimate" in the Issues and Description sections of the executive summary regarding activities under the current and proposed regulatory framework is inaccurate and does not acknowledge that substances or medications may be accessed outside of the regulatory framework for legitimate reasons. The use of the word "legitimate" implies that all activities that exist outside of the regulatory framework are illegitimate. However, diversion of medications such as hydromorphone, buprenorphine and methadone to opioid-tolerant individuals can function as a vital form of community support for individuals experiencing withdrawal, given that the alternative to manage withdrawal is accessing an unregulated and volatile drug supply and that access to treatment and care more broadly is generally poor.

International human rights bodies have acknowledged that medications such as buprenorphine and methadone are essential medicines that are often restricted excessively, which conflict with the universal right to health. Further, in one example, research modelling in 2023 by Adams et al. in the Harm Reduction Journal "Examining buprenorphine diversion through a harm reduction lens"*, demonstrates that increased buprenorphine diversion is not associated with increased overdoses and can function as community-based care in a context of unmet healthcare needs. The use of diverted substances as a form of support and care in addressing unmet healthcare needs, particularly within a context of having poor access to medications and treatment, was also reported in an article published July 22 2024 in the Toronto Star "She'd never heard of fentanyl before the police knocked on her door."* Rather than referring to activities under the regulatory framework as "legitimate", "legally-sanctioned" would be a more accurate and less stigmatizing term to use.

Second, while the proposed CSR seeks to address evolving practice, it does little to provide innovative regulatory mechanisms to address the toxic unregulated drug crisis. While we commend that some progress has been made to support pharmacists as medication experts in the proposed CSR, additional regulatory pathways are needed to enhance access to health services and goods, such as including nurses and pharmacists in the definition of practitioners, as discussed below. New regulatory pathways to provide regulated alternatives to the unregulated drug supply are urgently needed to improve public health and safety. The proposed CSR also fails to meaningfully address both Canada's human rights obligations and the unmet healthcare needs of the hundreds of thousands of people regularly accessing the unregulated drug market in Canada. Further, regulatory schemes should provide opportunities for communities that have been most harmed by drug criminalization to participate in the legal market as licensed dealers, producers, processors etc.

RECOMMENDATIONS

- Change all instances of "legitimate" with "legally-sanctioned" throughout all explanatory materials and the CSR.

- Review the CSR in its entirety to ensure it is sufficiently flexible to support novel, evidence-supported pathways of access to legally-sanctioned regulated psychoactive substances for medical and scientific purposes. The CSR requires a comprehensive review based on an accurate assessment of the public safety and public health risks posed by the unregulated drug supply. We provide some detailed recommendations below based on Canada's human rights obligations under international and domestic law to initiate this process. However, the character limitations of this submission, and the scope of the feedback requested by Health Canada, do not allow us to make complete revisions.

- Support the participation in the legal market for communities that have been most harmed by drug criminalization through legislative flexibility (outlined below) and proactive equity-focused programming. Some of our recommendations below address this issue directly. Once again, however, much more will be required to ensure the CSR is capable of being interpreted and implemented in a manner consistent with equity and human rights obligations. It is our hope that our initial feedback, including the multiple peer reviewed sources and grey literature we provide in the emailed pdf will offer guidance to Health Canada as it undertakes a comprehensive review of the CSR.

**Issues (20,000)**

This section begins "*The Canadian legislative and regulatory framework for controlled substances has evolved over decades to address emerging issues and meet international commitments under the United Nations international drug control Conventions."* Two issues arise:

First, UN Drug Control Conventions* are not static and are currently the subject of significant debate among UN Member States (States), with some States formally problematizing or rejecting aspects, or the entirety, of them. Some States are considering, or have implemented, policy reforms despite these being in tension with UN Drug Control Conventions. For instance, due to the cultural significance of the coca leaf and international treaties to respect the rights of Indigenous Peoples, the cultivation* of coca has been decriminalized in Bolivia; several States have legalized recreational and or medicinal cannabis*; and there is growing divergence as to the legal status of psychedelics*.

Second, the rationale for reforms recognizes that UN Drug Control Conventions contradict States' human rights obligations and negatively impact the progressive realization of health, sustainable development and environmental protection goals. States' human rights obligations are detailed in various UN human rights treaties, to which Canada is a signatory. In recent years, a range of international bodies such as the UN Office of the High Commissioner for Human Rights (OHCHR) have challenged the UN drug control regime*, pointing to its deleterious impacts for people who use drugs and other marginalized groups throughout world, particularly women, people of African descent and Indigenous Peoples, as well as environmental damage and the incentivization of crime and corruption. There is growing global awareness of the harms of enforcement-based approaches to drug control, particularly when contrasted with human rights obligations and sustainable development goals.

These developments have destabilized consensus among States about the appropriateness and continued feasibility of UN Drug Control Conventions. Given these evolving debates, the proposed CSR may require imminent revisions. It is important to note that Canada has latitude under UN Drug Control Conventions, and they must be interpreted in light of Canada's human rights commitments. Relatedly, the issue of drug decriminalization in international discourse has informed our recommendations. While decriminalization of unregulated drugs is not at issue in the CSR directly, Canada's current criminal enforcement-based drug control efforts have contributed to stark inequities, such as the prevalence of criminal records within Indigenous, Black and other equity-denied communities; amendments to the CSR could mitigate these. We provide a non-exhaustive summary of recent international developments that elucidate the tensions between criminal enforcement-based approaches and modern human rights standards. We urge consideration of their possible ramifications for Canada's drug control regime and the proposed CSR.

In April 2016, the UN General Assembly unanimously adopted the Outcome Document* of the special session on the world drug "problem". It contained over 100 operational recommendations

in seven thematic chapters, focused on demand and supply reduction; the availability of controlled substances for medical and scientific purposes; human rights; challenges and new trends; international cooperation and development.

In 2018, in response to the Outcome Document, the UN System Chief Executives Board for Coordination adopted the "United Nations system common position supporting the implementation of the international drug control policy through effective inter-agency collaboration"*, featuring eight shared principles that support the Outcome Document and the 2030 Agenda for Sustainable Development.

In 2019, Ministers and government representatives participating in the ministerial segment of the 62nd CND, adopted the "Ministerial declaration on strengthening our actions at the national, regional and international levels to accelerate the implementation of our joint commitments to address and counter the world drug problem"*. States reiterated their *"commitment to respecting, protecting and promoting all human rights, fundamental freedoms and the inherent dignity of all individuals and the rule of law in the development and implementation of drug policies."* They resolved to review the Declaration in 2029 and committed to a mid-term review in 2024.

Also in 2019, a coalition of States, UN entities and leading human rights experts launched a landmark set of international legal standards "International Guidelines on Human Rights and Drug Policy (the Guidelines)" *. The Guidelines, based on extensive legal research and expert analyses of international human rights instruments and mechanisms, reflect tensions elicited by trying to advance global drug control efforts while simultaneously respecting human rights.

The Guidelines harness the universal nature of international human rights principles and States' obligations to uphold them, offering a comprehensive spectrum of drug policy recommendations that should, or could, be adopted by States. Two recommendations that should be adopted are "*Repeal, amend, or discontinue laws, policies, and practices that inhibit access to controlled substances for medical purposes and to health goods, services, and facilities for the prevention of harmful drug use, harm reduction among those who use drugs, and drug dependence treatment"*, and *"Consider reviewing the 1961 and 1971 drug control Conventions' schedules of substances under international control in light of recent scientific evidence, and prioritise exploring the medical benefits of controlled substances in accordance with the World Health Organization's scheduling recommendations."*

The Guidelines also state *"decriminalis[ation of] the possession, purchase, or cultivation of controlled substances for personal consumption"* could be adopted without contravening UN Drug Control Conventions. Decriminalization is a policy intervention that would promote compliance with civil and political rights; the rights to the highest attainable standard of health, privacy, freedom of thought, conscience, and religion; women's right to health; the rights of Indigenous Peoples to traditional medicine and health practices; and the rights of minors. The Guidelines represent a significant departure from traditionally accepted approaches to drug control and, if adopted, would notably advance the UN's 2030 Sustainable Development Goals*.

Also in 2019, the UN Human Rights Council (UNHRC) requested the UN Working Group on Arbitrary Detention to prepare a study on arbitrary detention relating to drug policies. Consultations were held with the UN Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB) and other stakeholders. The study "A/HRC/47/40: Arbitrary detention relating to drug policies Study of the Working Group on Arbitrary Detention"* was delivered to the UNHRC's 47th session in 2021 and found that enforcement approaches to drug control result in a wide range of human rights violations including arbitrary detention, torture, lack of observance of free trial guarantees, disproportionate sentencing including the death penalty, bans on suspended sentences, parole, pardons, and amnesty, and misuse of drug control to target human rights defenders, journalists and political opponents. It noted with concern that "*the war on drugs may be understood to a significant extent as a war on people"* and emphasized that the impact of drug enforcement is greatest on those who are poor especially within communities of racial and ethnic minorities, Indigenous Peoples, migrants, women, lesbian, gay, transgender, and intersex people, victims of human trafficking, and children. The conclusions of the study were not directed to any one nation or region of the world – rights violations due to enforcement approaches to drug control were found to be universal.

The study also noted:

> "*While the 1988 Drug Convention provides for the criminalization of personal use or possession for personal use of drugs, it allows for an exception to criminalization where it is incompatible with a State's constitutional principles and the basic concepts of its legal system (art. 3 (1) (c)).*" It reiterated statements from the Working Group that "*criminalization of drug use or consumption should be avoided by all States",* and *"Drug use and dependence should not be treated as a criminal matter, but rather as a health issue, and addressed with rights-based measures, particularly measures based on the right to health enshrined in article 12 of the International Covenant on Economic, Social and Cultural Rights."* The study concludes with 17 recommendations for States, the first of which is *"Decriminalize the use, possession, acquisition or cultivation of drugs for personal use, including the possession of associated paraphernalia."*

Following this, during the 50th session of the UNHRC in 2022, and ahead of the International Day Against Drug Abuse and Illicit Trafficking on June 26, 2022, UN human rights Rapporteurs and other experts called on the international community to end enforcement-based approaches. It urged States and all UN agencies to ground their drug policies in international human rights law and standards, issuing the following statement*:

> *"Data and experience accumulated by UN experts have shown that the 'war on drugs' undermines health and social wellbeing and wastes public resources while failing to eradicate the demand for illegal drugs and the illegal drug market. Worse, this 'war' has engendered narco-economies at the local, national and regional levels in several instances to the detriment of national development. Such policies have far-reaching negative implications for the widest range of human rights, including the right to personal liberty, freedom from forced labour, from ill-treatment and torture, fair trial rights, the rights to*

> *health, including palliative treatment and care, right to adequate housing, freedom from discrimination, right to clean and healthy environment, right to culture and freedoms of expression, religion, assembly and association and the right to equal treatment before the law."*

Also during the 50th session of the UNHRC, the OHCHR presented "A/HRC/50/53: Human rights and HIV/AIDS - Report of the United Nations High Commissioner for Human Rights"*. The report acknowledged that "*people who use drugs are criminalized, marginalized and stigmatized in most countries, resulting in significant barriers to access to health services (including those for HIV) and in other human rights violations."* It noted the unique violations faced by women who use drugs and urged States to end compulsory drug detention and treatment, repeal mandatory minimum sentences for drug offences, ensure access to harm reduction, and guarantee the meaningful engagement and leadership of community-led organizations in development, monitoring, and implementation of relevant laws and policies. The gravity of this last recommendation prompts us to consider whether people who use drugs were meaningfully engaged in the development of the proposed CSR.

In 2023, the UNHRC requested OHCHR to prepare a report on human rights and the world drug problem as a contribution to the 2024 mid-term review. The report "A/HRC/54/53: Human Rights Challenges in Addressing and Countering all Aspects of the World Drug Problem"*, prepared in consultation with States, the UNODC, UN agencies, and civil society, is built on the 2019 Guidelines. Published in 2023, it was described as groundbreaking* and landmark* and represents a historical rupture from the norms and institutions of the international drug control regime. It declared drug control efforts based on enforcement fuel widespread human rights violations, stating "*Rather than a 'war on drugs', what is needed is a focus on transformative change..."* The primary areas of concern it raised about enforcement are the lack of and unequal access to treatment and harm reduction, the militarization of drug control, overincarceration and prison overcrowding, the use of the death penalty for drug-related offences, and the disproportionate impact of punitive drug policies on youth, people of African descent, Indigenous Peoples and women.

The report emphasized that new approaches to drug control are critical. It consolidated a growing body of recommendations provided by UN human rights experts, expressing strong support for decriminalization and recommending that States consider *"developing a regulatory system for legal access to all controlled substances"* to address the links between the war on drugs, organised crime, economic and social insecurity, and environmental degradation. This is the first time a UN body has expressly stated that legal regulation is an advisable approach to drug control.

The report was issued amid significant drug policy developments among States. In 2023, Bern, Switzerland approved a motion* to conduct a scientific pilot trial of controlled cocaine sales and extending a two-year trial of regulated cannabis sales; a nod to the legacy of Switzerland being the first State to offer heroin-assisted treatment* in 1994. About the decision, Juan Fernández

Ochoa, of the International Drug Policy Consortium (IDPC), said* "*I think it's an incredibly positive move....it suggests a shift in the mood of what elected officials are willing to discuss."*

At the 66th CND, Vice-President of the Plurinational State of Bolivia, Jilata David Choquehuanca, activated the process to review the classification of the coca leaf as a narcotic drug in Schedule I of the Single Convention on Narcotic Drugs. An annex* to the formal notification states "*The inclusion of the coca leaf as a narcotic drug in Schedule I of the 1961 Convention, as well as the treaty obligation to abolish coca chewing, represent a grave historical error with severe social impacts and infringements on indigenous and cultural rights."* On November 30, 2023, the Director-General of the World Health Organisation (WHO) announced* that the WHO would conduct a 'critical review'* of the coca leaf by forming a committee of international experts in different fields which, based on its findings, may recommend changes in coca's classification under UN Drug Control Conventions. These recommendations would be submitted for approval by the CND, likely in 2025. The prospect of removing the coca leaf from the 1961 Convention has triggered further discussions about how global drug policies contravene the rights of Indigenous peoples and human rights.

Human rights were also central at the 67th CND. As reported in The Lancet*, the UN High Commissioner for Human Rights, Volker Türk, urged that global drug policy be rooted in human rights and aligned with Sustainable Development Goals. For the first time at CND, a resolution* was adopted by States recognizing harm reduction as a crucial component of humane and effective drug policies. Commenting on the resolution, the UN Joint Programme on HIV/AIDS (UNAIDS) welcomed* it as another landmark in the *"political commitment to a rebalancing of drug policy towards a public health approach",* one that is critical for meeting the targets in the 2021-2026 Global AIDS Strategy*.

At this session of CND, the planned mid-term review of the 2019 Ministerial Declaration was conducted. The review was critiqued* by the IDPC as unambitious, as noted in a shadow report* published by the IDPC in October 2023. The shadow report lays out recommendations for the global drug control regime to replace "eradication goals" with a strong call for global drug policies to contribute meaningfully to the achievement of the 2030 Agenda for Sustainable Development and to acknowledge the existence of legally regulated markets for the non-medical use of controlled drugs. It calls for periodic, evidence-based monitoring of, and reporting on, the security, health, human rights, and development impacts of such markets by relevant UN bodies, with contributions from civil society, academia and States.

The IDPC sentiments were echoed during the the mid-term review when a coalition of 62 States led by Colombia delivered a joint statement* calling for urgent changes in global drug policy. The statement encourages the international community to *"put people first"* by upholding human rights and dignity and increasing investment in comprehensive, inclusive, and sustainable alternative development programs. The statement also reiterates support for the implementation of the 2019 Guidelines and the 2022 UN High Commissioner for Human Rights' 2022 report. The statement concludes "*If we want to impact the lives of individuals, households, and*

*communities around the globe, we need a transformation in our vision of the world drug policy, based on a realistic evidence-based assessment and a pragmatic response."*

Shortly thereafter, at the 56th session of the UNHRC in 2024, the UN Special Rapporteur on the Right to Health presented "A/HRC/56/52: Drug Use, Harm Reduction, and the Right to Health"*. The report explores harm reduction policies and practices for drugs whose production, distribution and consumption have been subject to the UN Drug Control Conventions, including how the approach to such control has negatively affected the availability, accessibility, acceptability and quality of certain drugs used as medicines. It asserts *"the harms related to drug use have been fueled by ill-advised legal and political strategies, part of the 'war on drugs' led by the global North,"* and underlines the *"need for States to move from a reliance on criminal law and instead take a human rights-based, evidence-based and compassionate approach to harm reduction in relation to drug use and drug use disorders."* To uphold the universal right to health, the Special Rapporteur urged nations to abandon punitive approaches to drugs and to *"decriminalize, repeal, rescind or amend laws and policies that have a negative impact on the right to health and that perpetuate different systems of oppression, such as racism and colonialism."*

On June 26 2024, to mark "World Drugs Day", Amnesty International launched "Time for change: advancing new drug policies that uphold human rights"*, calling for drug policies that better uphold human rights. Amnesty International called on States to *"adopt new models of drug control that put the protection of people's health and other human rights at the centre, including the decriminalization of the use, possession, cultivation and acquisition of drugs for personal use, and the effective regulation of drugs to provide legal and safe channels for those permitted to access them."*

These are a few examples of how thinking is changing regarding international drug control. The contradictions of seeking to uphold human rights under international law while enforcing the war on drugs are being discussed openly. Increasingly, expert calls to approach drug regulation through the lenses of public health and human rights are being incorporated into official documents at the UN and by international bodies. The proposed CSR must keep pace with this rapidly changing discursive and legal landscape. We provide suggestions for doing so.

RECOMMENDATIONS:

- Redraft the executive summary, issues, background and objectives to incorporate this overview and to reflect the dynamic nature of UN Drug Control Conventions.

- Ensure the CSR is sufficiently flexible to meet noted international human rights standards.

- Acknowledge the ways UN Drug Control Conventions are inconsistent with international human rights Conventions. Foreground Canada's commitment to the progressive realization of international human rights standards in the contextual materials and content of the CSR.

**Background (20,000)**

Our first concern is procedural. It states Health Canada engaged in public consultations on certain aspects of the proposed CSR, with no details on the nature of the consultations and the extent to which people with lived and living experience of criminalized drug use were consulted. Given the scale, scope and anticipated impact of the CSR, we request a detailed description of which stakeholders were consulted, what was asked, when and where consultations were held, and how stakeholder feedback was analyzed, synthesized and incorporated into the proposed CSR. We hope to see the inclusion of the methodology in the final version.

Next, this section does not accurately capture the purposes and practical outcomes of the Controlled Drugs and Substances Act (CDSA)*. It is misaligned with historic and contemporary analyses of how drug laws and regulations impact people in Canada. This is exemplified in the opening sentence: *"The Controlled Drugs and Substances Act (CDSA) provides a legislative framework for the control of substances that can alter mental processes and that pose risks to public health and public safety when used inappropriately or diverted to the illegal market."* The phrase "*substances that can alter mental processes"* is used synonymously with *"illegal drugs"*; however, many legal substances also alter mental processes (e.g. alcohol, prescription drugs). Moreover, it is not clear what is meant by *"inappropriately"*. The word is value-laden and should be replaced to more clearly convey that what is being referenced is a substance's legal status (as already stated, the word *"legitimate*" used throughout presents the same issues). A more appropriate and accurate phrasing would be: "psychoactive substances that are currently deemed illegal".

As noted, diversion of medications such as hydromorphone, buprenorphine and methadone to opioid-tolerant individuals can function as a form of care when supporting an individual experiencing withdrawal. Given that access to treatment and care more broadly is generally poor across Canada, the alternative to manage withdrawal is accessing an unregulated and volatile drug supply. Diversion of substances that are currently deemed illegal, particularly within the context of widespread unmet healthcare needs and lack of access to essential medicines, does not necessarily pose greater risks to public health and safety than the risks associated with accessing the unregulated drug supply. Research* has shown that diversion tends to occur among opioid-tolerant individuals, and that sharing substances such as buprenorphine is not associated with increased overdoses even when accounting for the possibility of diversion to some opioid-naive individuals. International human rights bodies have acknowledged that medications such as buprenorphine and methadone are essential medicines that are often restricted excessively, which conflict with the right to health. Therefore, describing all cases where substances are diverted to the illegal market as posing a risk to public health and safety is inaccurate, stigmatizing and in conflict with public health interests.

It also is important to acknowledge that legal substances, including alcohol, cannabis, tobacco and prescribed medications, have the potential to threaten public health and safety. The health and safety risks referenced in the Background, however, focus on the legal status of certain drugs, despite growing understanding that the greatest risk to Canadians is not derived from the

mere consumption of illegal substances. Rather, risks are caused and exacerbated by the fact that illegal substances are consumed under a policy and legal framework that prevents their quality control, regulatory oversight and informed consumption. For instance, fentanyl is safely used in medicine yet results in significant harm when unregulated due to unknown dosages and purity levels. To complement our remarks in the Issues section about international drug control debates, a non-exhaustive summary of domestic processes on drug policy and their implications for the CSR are included.

Well before the CDSA, the Commission of Inquiry into the Non-Medical Use of Drugs (the "Le Dain Commission") was initiated in 1969 due to growing awareness of the non-medical use of drugs. It held two public hearings and received 639 submissions from a range of experts, among them federal and provincial government departments, law enforcement authorities, educational institutions and associations, and medical and pharmaceutical institutions and associations. A final report* was released in 1973.

The Le Dain Commission was an early and monumental attempted intervention in legislative approaches to drug use. It thoroughly detailed the economic, social and individual costs of criminalization, highlighting the costs of law enforcement, courts and incarceration. It also identified sweeping police powers as a social cost and discussed the human rights costs of economic penalties (e.g. fines, prison terms, employment impacts). The Le Dain Commission concluded that these costs were not accompanied by proportional benefits and strongly recommended a gradual withdrawal from criminal sanctions against people who use drugs, and adoption of less coercive and less costly alternatives.

In 1987, amid growing discussion of the serious limitations of law enforcement in reducing the demand for drugs, the federal government announced a five-year "National Drug Strategy: Action on Drug Abuse"*. Subsequently, there were modest but inadequate attempts to reorganize the government agencies responsible for drug regulations. Dr. Diane Riley, in a 'review and commentary'* for the Special Committee on Illegal Drugs in 1998, characterized these as having *"the unintended effect of creating even more problems of coordination between levels of government than before."* According to Riley, the strategy *"was clearly influenced by the latest American 'War on Drugs'"*, without reorienting Canada's dominant approach to drug policy in a meaningful way.

The Special Committee on Illegal Drugs* published its summary report "Cannabis: Our Position for a Canadian Public Policy"* in 2002. The report established the Committee's mandate as a continuation of the 1996 passing of the CDSA and emphasized that while the CDSA was being developed, the *"vast majority of witnesses were highly critical of [it]."* The volume and magnitude of these criticisms were such that the Senate Committee *"propose[d] energetically the creation of a Joint Committee of the House of Commons and the Senate that would review all Canadian drug legislation, policies and programs."* However, this process did not materialize. Another motion to engage in a similar process was adopted by the Senate in 2000 and abandoned after the 2000 general election. In the 2002 report, the Special Committee expresses its dissatisfaction with the narrowness of the mandate to evaluate cannabis legislation alone.

The report stated "*cannabis has not been approved as a medicinal drug in the pharmacological sense of the word. In addition to the inherent difficulties in conducting studies on the therapeutic applications of cannabis, there are issues arising from the current legal environment and the undoubtedly high cost to governments of conducting such clinical studies."* This statement can contemporaneously be applied to all illegal drugs and has implications for the CSR, particularly given the CSR's repeated references to *"illegitimate"* uses of substances. As the Committee relayed in 2002, many substances that may have scientific, medicinal and other uses cannot be scientifically evaluated through traditional research processes because of the current legal environment. Ongoing legal barriers to evaluation must thus be interrogated.

The report then recommended a range of interventions including making cannabis available for recreational and therapeutic use while implementing rigorous procedures for scientific monitoring and evaluation. Additionally, it spoke directly to Canada's international position. The report acknowledged that legally regulating cannabis would be in contravention of the UN Drug Control Conventions and suggested that Canada "*temporarily withdraw from the Conventions or accept that it will be in temporary contravention until the international community accedes to its request to amend them,"* recommending the second course of action because the UN Drug Control Conventions promote north-south inequities. According to the report, Canada "*could use this imbalanced situation to urge the international community to review existing treaties and Conventions on psychoactive substances."* As early as 2002, the Canadian Senate Committee was amply aware of the limitations of international drug control regimes and the domestic policies that flow from them.

In 2000-2020, several challenges were lodged against Canada's overarching drug control regime that resulted in legislative amendments. These included the opening and operating of Canada's first federally exempted safe injection site, Insite*, in 2003. Insite was the subject of intensive legal scrutiny and political debate culminating in a 2011 judgement by the Supreme Court of Canada* finding that a Ministerial decision to close Insite violated the *Canadian Charter of Rights and Freedoms* for those who accessed its services. This is a pressing example of how drug control regulations can and must be drafted, implemented and interpreted consistently with human rights standards.

In 2005, Canada became the first North American jurisdiction to implement a heroin-assisted treatment (HAT) clinical trial. The North American Opiate Medication Initiative (NAOMI)*, modeled after similar trials held in Europe*, compared the use of diacetylmorphine (i.e. heroin) to methadone. A similar trial in 2011, the Study to Assess Longer-term Opioid Medication Effectiveness (SALOME)* compared treatment with diacetylmorphine to hydromorphone. To run these trials, Health Canada granted requests for access to non-marketed drugs by practitioners for emergency treatment for specific patients under the Special Access Programme (SAP)*. In 2013, amendments were made that defined diacetylmorphine as a "restricted drug" under Part J of the Food and Drug Regulations (FDR) and prohibited the sale of any "restricted drug" under the SAP. A 2013 legal action challenged the constitutional validity of these amendments resulting in an interlocutory injunction* temporarily permitting continued access to

diacetylmorphine under the SAP. In light of this ruling, amendments were made to regulations under the CDSA* - the FDR, the NCR and the New Classes of Practitioners Regulations. In 2015, the government of the day overturned the policy on SAP applications, reinstating access to diacetylmorphine.

While the legacy of the NAOMI and SALOME trials is complex, they instigated further discourse about current drug policy regimes and again demonstrated the practical ability to evolve Canada's substance regulations. A more contemporaneous example of the evolutionary potential of drug control regulations is the Health Canada Subsection 56(1) class exemption* for patients, practitioners, and pharmacists prescribing and providing controlled substances issued in November 2021. Since the exemption was issued, pharmaceutical-grade alternatives to the illegal drug supply have been available to eligible residents of BC and to residents of some other provinces and territories who are enrolled in clinical trials. Although the class exemption was issued on a temporary basis, it demonstrated yet again that Health Canada can regulate to accommodate the emergency nature of the unregulated drug crisis.

The above changes emerged against a backdrop of reorientations to Canada's approach to substance use. In 2016, the Minister of Health announced that the Canadian Drugs and Substances Strategy (CDSS)*, would replace the former National Anti-Drug Strategy, adding harm reduction as a core pillar. By 2018, however, it was clear the CDSS was failing to achieve its stated purposes of preventing drug use, reducing stigma, supporting innovative approaches to treatment, and addressing illegal substance production, supply, and distribution. Therefore, in 2018, Health Canada launched a 90-day consultation to investigate how the CDSS could be improved. The consultation was welcomed by experts* who had long problematized the CDSS's overreliance on enforcement. A final report, "What We Heard: Strengthening Canada's Approach to Substance Use Issues"* concludes with the promise to closely review and consider the ideas and experiences shared during the consultations and to move forward with a public health focus on substance use. Notably, language used in the currently proposed CSR, including references to substance use as *"illegitimate"*, was widely problematized as being stigmatizing during the consultation.

Also in 2018, the federal government launched "Addressing the Opioid Crisis" (the "Opioid Initiative"), a horizontal complementary initiative to the CDSS. An evaluation* of the Opioid Initiative and CDSS published in August 2023 examined all funded partners' activities from 2017-18 to 2021-22. It concluded that substance use related harms continue to be *"alarming"* despite some progress made toward framing substance use as a public health matter. The evaluation further implied that ongoing efforts to decrease the diversion of drugs *"through regulatory actions like the accelerated scheduling of novel precursor chemicals, compliance promotion, and compliance and enforcement actions in relation to licensed dealers and pharmacies"* have not reduced the harms of the unregulated drug supply. Conversely, the evaluation found that "*the increasing toxicity of illegal drugs in Canada is an ongoing issue that is not only leading to an increase in overdoses, but also further complicating the federal government's ability to address the crisis through public health and public safety efforts",* and that "*there are challenges with respect to the increasing illegal importation of precursor*

*chemicals used in the production of illegal drugs in Canada and the regulatory regime's capacity to keep pace with the composition of chemicals produced and sold by organized crime groups."*

In spring 2021, under the mandate of the CDSS, and amid escalating rates of overdose during the COVID-19 pandemic, Health Canada established an Expert Task Force on Substance Use *(the "Task Force"). The Task Force provided Health Canada with independent, expert recommendations on the federal government's drug policy. It submitted two reports. The first, "Report 1: Recommendations on Alternatives to Criminal Penalties for Simple Possession of Controlled Substances"* was published in May 2021. The Task Force was mindful of five core issues - stigma; disproportionate harms to populations experiencing structural inequity; harms from the illegal drug market; the financial burden on the health and criminal justice systems; and unaddressed underlying conditions – as well as Canada's obligations under international treaties. Not only did the report assert unequivocally that "*criminalization of simple possession causes harms to Canadians and needs to end"*, it offered a range of recommendations pertaining to decriminalization and regulation. In addition to ending criminal penalties and all coercive measures for simple possession, key recommendations include ensuring that *"criminal records from previous offenses related to simple possession be fully expunged"*; and "*the Government of Canada immediately begin a process of legislative change to bring the [CDSA], the Tobacco and Vaping Products Act (TVPA), the Cannabis Act, and any other relevant federal legislation under a single public health legal framework with regulatory structures that are specific to different types of substances."* This latter recommendation could have had profound consequences for the proposed CSR but has not been adequately contemplated, let alone adopted.

The Task Force's second report, "Recommendations on the Federal Government's Drug Policy as Articulated in a Draft Canadian Drugs and Substances Strategy (CDSS)"* was published in June 2021. It articulated that "*people who use substances are not the problem"* and that "*the war on drugs has led to what ends up looking like a war on people who use drugs."* As such, it asserts that "*bold actions are urgently needed"* and "*Canadian policy on substances must change significantly to address and remove structural stigma, centre on the health of people who use substances, and align with current evidence."* To this end, it recommended "*Includ[ing] as a core priority of the CDSS to immediately develop and implement a single public health framework with specific regulations for all psychoactive substances, including currently illegal drugs as well as alcohol, tobacco, and cannabis. This framework should aim to minimize the scale of the illegal market, bring stability and predictability to regulated markets for substances, and provide access to safer substances for those at risk of injury or death from toxic illegal substances."*

This groundbreaking recommendation aligns with a growing international and domestic chorus calling to advance human rights, especially the rights of Indigenous Peoples, racialized communities, gender minorities, and other marginalized communities, by ushering in a sea change in Canada's drug policy regime. Despite the Task Force being established by Health Canada, the CSR does not incorporate its conclusions. This lacuna is notable, particularly because in the last year alone, and building on the Task Force's reports, government and government-adjacent entities including the British Columbia (BC) Coroners Service*, the BC

Provincial Health Officer* and the Ontario Chief Medical Officer of Health* have also recommended that regulations be amended to allow consumers to access pharmaceutical-grade alternatives to the unregulated drug supply. We encourage amendments to the CSR that will accurately reflect contemporary and historic recommendations issued by experts. We will not solve the unregulated drug crisis without a bold and urgent paradigm shift.

RECOMMENDATIONS:

- Provide the methodology undertaken for public consultation for the development of the CSR.
- Acknowledge that though the CDSA was developed to comply with UN Drug Control Conventions, the Conventions have limitations and are inconsistent with international human rights conventions.
- Ensure language describing the CDSA is accurate and reflects contemporary human rights analyses:
    - 1) Instead of describing substances scheduled under the CDSA as *"substances that can alter mental processes and that pose risks to public health and public safety when used inappropriately or diverted to the illegal market"*, replace with more accurate language, such as "psychoactive substances that are currently deemed illegal"; and
    - 2) Replace all references to *"legitimate"* use of substances with "legally-sanctioned".
- Remove all language where diversion is described as necessarily equating to public health and safety risks (detailed below).
- Clearly delineate the risks of accessing the unregulated market and mandate the consideration of how diversion can provide alternatives to the unregulated market, especially within the context of widespread unmet healthcare needs and lack of access to essential medicines.
- Rather than describe restricted substances such as certain amphetamines and psychedelics as having no therapeutic use, acknowledge that clinical research is underway to establish possible therapeutic uses (e.g. psilocybin). Also acknowledge that the current regulatory regime increases barriers and costs associated with conducting clinical studies and amend the CSR to improve access to substances for research purposes.

**Objective (20,000)**

Add:

- To bring Canada's regulatory scheme into better compliance with current understandings of public health and safety and evolving understandings of international drug control systems;

- To ensure that the Canadian regulatory regime for psychoactive substances regulated under the CDSA is consistent with the progressive realization of the right to health and other international human rights standards and the promotion of health and economic equity;

- To support lawful pathways of access to regulated substances.

**Description (20,000)**

Here we outline how the above themes manifest in various sections of the CSR to contextualize our proposed revisions.

*Interpretation:*
The Description only addresses consolidation and clarification, not the need to address emerging gaps and issues. We provide a brief rationale for recommended amendments to address some gaps.

Defining "Prescription": Under section 2(2) of the current NCR, a prescription is defined as "*an authorization given by a practitioner that a stated amount of a narcotic be dispensed for the person named in it or the animal identified in it."* Similarly, the proposed CSR defines a prescription as "*an authorization given by a practitioner that a stated amount of a controlled substance, other than a restricted drug, be sold or provided for the individual named or the animal identified in it"* and provides that *"A practitioner may issue a written prescription that they sign and date or a verbal prescription if … the practitioner is treating, in their professional capacity, the individual for whom or animal for which the prescription is issued; and the controlled substance set out in the prescription is needed to treat the individual's or animal's medical condition."* Based on the NCR's definition of "prescription" at least one nursing college* has interpreted this as requiring orders for controlled substances to be client specific, thus precluding medical directives* to guide prescribed pharmaceutical alternatives.

As discussed in a 2024 HIV Legal Network report "How to Innovate in an Emergency: Legal and Policy Measures to Scale Up Safe Supply at Supervised Consumption Services"*, medical directives could facilitate prescribing to qualified participants, which already exist for the administration of controlled substances for palliative care*. Enabling practitioners to confer their authority to prescribe to other care providers (without a direct contemporaneous assessment by the authorizer) would be subject to regulatory college oversight and limited to clients with identified health conditions in specified circumstances. Such a medical directive would be in line with a recent report* from the Office of the BC Provincial Health Officer urging "*an exploration of options [for prescribed alternatives programs] that are less resource intensive and don't require 1:1 prescribing."* This requires an amendment to the CSR definition of "prescription" allowing the dispensation of a controlled substance to a specified person or a class of people.

*Licensed dealers*:
The following public safety analysis informs the significant amendments proposed to the licensing provisions of the CSR. We fully understand the need for public safety to be a core priority of the CSR. However, the concept of public safety in the CSR is narrow, linked almost exclusively to the risk of diversion, and undermines public safety in practice. A growing body of literature, as well as international and domestic discourse (see above), suggest a more expansive approach to public safety would produce more desirable outcomes.

To contextualize recommendations below, we briefly elaborate on how public safety is defined and operationalized within mainstream scientific and international human rights communities. Just as the WHO defines public health as "*more than just the absence of mental disorders or disabilities*"*, public safety is generally not defined as the mere absence of violence, crime and unnatural death. Rather, social scientists and human rights NGOs* adopt a more comprehensive understanding* of public safety, emphasizing the positive presence of physical, emotional and material security and supports. This raises concerns of framing safety throughout the CSR solely in negative terms and with a singular focus on the risk of diversion as the primary threat to public safety. Thus, we define risks to public safety as the risks of overdose, interpersonal violence and organized criminal activity, and effective risk reduction as publicly funded supports and policies that promote physical, emotional and material security for all people.

Regarding the risk of overdose, the CSR's preoccupation with diversion ignores that almost all overdose fatalities in Canada are due to the unregulated drug supply. There is no evidence to date that diverted pharmaceutical drugs contribute to fatal overdoses. Rather, data indicate that diversion of prescribed alternatives may protect consumers from fatal and non-fatal overdose (see above). According to Health Canada's webpage (modified March 2024) "Canada's overdose crisis and the toxic illegal drug supply"*, "*Some opioids are prescription drugs, used to treat pain and other medical conditions. However, most of the overdose deaths in Canada involve opioids produced illegally."* It also states "*One of the factors contributing to Canada's high rates of opioid-related overdoses is the toxic and unpredictable illegal drug supply. Potent opioid and non-opioid substances keep being mixed into the supply. This creates more uncertainty about the type and amount of drugs that are circulating and being consumed."*

Health Canada is aware of the risks to public safety caused by the unregulated drug supply and should incorporate this analysis into the CSR. Protecting against the diversion of pharmaceutical drugs to opioid-naïve consumers or to profit seeking illegal entities are valid goals of the CSR. However, data regarding the prevalence of diversion to opioid-naïve consumers is wholly lacking and the risk to an opioid-naïve person from ingesting a substance from the unregulated supply is far more dire. Further, limiting the diversion of pharmaceuticals into criminal profit generating activities must be balanced against the risk posed by the unregulated supply.

The proposed licensing scheme appears to rely on two sequential falsehoods: 1) Denying, revoking or suspending a license will prevent diversion, and 2) Preventing diversion will mitigate the risk of overdose. This appears to be based on the unfounded premise that illegal drug markets do not exist already. Granting a license will not create a novel illegal drug market, and any Ministerial directive to withhold a license based on diversion concerns is detached from the reality that illegal substances are in wide circulation presently. It is these illegal, unregulated substances that pose the biggest risk to public safety.

Requirements that the Minister refuse, revoke or suspend a license if they suspect substances may be diverted could contradictorily exacerbate the risk of overdose fatalities. Abrupt disruptions to the legal drug market are a fundamental reason Canada is experiencing an overdose emergency. Recent efforts to reduce the circulation of legally prescribed opioids have

not been unreasonable given that some for-profit pharmaceutical companies had promoted prescription opioids with little regulatory oversight for decades. However, the rapid pace with which many patients were subsequently de-prescribed after becoming physically dependent* without adequate alternative supports led some people to resort to the illegal market.* Researchers in the U.S. hypothesize that government "crackdowns" on pharmaceutical prescriptions had the unintended market effect of positioning illegal opioids as a far cheaper, more accessible and more potent alternative.* Not only did this contribute to a sharp increase in overdose fatalities in the short term, it bolstered an existing transnational incentive structure for organized criminal groups to fill gaps left in the legal market. Canada and other nations are now contending with the long-term devastating consequences of these regulatory and legislative decisions.

A second risk to public safety is interpersonal violence. The CSR does not address the associations between illegal drug markets and interpersonal violence as a factor to be considered in licensing and other decisions. This is a striking omission. In addition to the multiple sources included in the "Issues" section, most of which point to the link between criminalization and interpersonal violence as a core reason for States to reconsider UN Drug Control Conventions, researchers identify two key mechanisms through which drug law enforcement promotes interpersonal violence.

Interactions between people who use or are suspected of using drugs and police can be violent. The effects of policies that criminalize drugs are felt most strongly by people from poor and racialized communities*, people who are disabled, and women and gender minorities* – the same communities that lack access to adequate health care, including prescribed medications regulated under the CSR. Research participants from these communities describe* being targeted by discretionary policing and experiencing persistent psychological terror regardless of whether they use drugs or not. These examples of how structural violence manifest as interpersonal violence should inform the CSR to improve access to essential medicines and decrease structural violence that may be caused or perpetuated by a limited framing of "public safety".

Further, disrupting the drug market through enforcement can cause or exacerbate interpersonal violence associated with drug-related debts*. Illegal economies revolve around undocumented transactions including loans or advances of substances or money with the expectation of repaying debts later*. When these cycles are disrupted, interpersonal violence can occur* because their debts are not repaid*. There is no evidence to suggest that preventing legal substances from entering the market or removing illegal substances from the market would reduce debt-related violence. It is thus unclear how the licensing scheme outlined in the CSR would minimize the risk of interpersonal violence – it may do just the opposite.

Finally, organized criminal activity is an upstream driver of interpersonal violence and is a predictable market response to drug prohibition and drug law enforcement. In a submission to the Senate of Canada Special Committee on Illegal Drugs*, Barrister and Solicitor Eugene Oscapella explains "*the inflated price of these drugs is purely a product of the black market produced by prohibiting them...Without prohibition, these drugs would sell for much, much less.*

*They would not present any significant opportunity for terrorist groups to profit from their production or sale."* Oscapella strongly recommends reformulating Canada's drug laws because "*focusing on traditional measures to suppress the drug trade, including law enforcement, crop substitution and measures to reduce the movement and laundering of drug money, will fail to significantly reduce the flow of drug money to terrorists."*

Beyond concerns of funding terrorism, numerous other profitable illegal markets are generated under the current regulatory scheme, with trickle down risks for people and communities that have devastated communities domestically and throughout the developing world. Academics, journalists and human rights advocates refer to regions, particularly in Latin America, where the state apparatus has been infiltrated and captured by drug trade actors as "narco-states," wherein militarized* enforcement has eroded democratic institutions. Western states, including Canada, fund the bulk of drug interdiction programs in the developing world while not experiencing many of the negative local social effects of these programs. The effects of Canada's domestic policies, including the CSR, cannot be separated from the international arena, and the CSR should operate to mitigate these transnational harms to the extent possible.

Any regulatory scheme that aims to minimize risks to public safety must engage with this evidence, including by amending the licensing scheme to promote and maintain legal pathways for responsible regulation. Sustainable and equitable public safety promotion also requires a holistic definition of public safety. Canada must uphold its commitment to investing public money for public good through regulations that produce robust, equitable access to physical, emotional and material security for all people.

Amending the CSR alone is not the mechanism by which to shift overarching governmental approaches to public safety, however, we provide specific recommendations to produce modest benefits.

*Practitioners:*
The CDSA and associated regulations* define "practitioners" to include professionals such as physicians and dentists, as well as any other person or class of persons prescribed as a practitioner, such as nurse-practitioners. The identification of those "prescribed" persons or classes is governed by regulation. It therefore falls within the ambit of the CSR to refine and update those prescribed persons/classes. We provide a rationale and recommendations for doing so below.

Practitioners prescribing pharmaceutical alternatives are predominantly physicians and nurse practitioners and currently there is a significant shortfall of practitioners available and willing to prescribe. Expanding the definition of a "practitioner" under the CSR to include other regulated professionals such as nurses and pharmacists may address the shortfall. Adding nurses to the definition of practitioners would, for example, enable them to prescribe alternative medications at supervised consumption sites - many already staffed by nurses. This would facilitate the scale-up of witnessed consumption of regulated substances in lower-barrier settings where people who use drugs and staff already have an established relationship of trust.

While the inclusion of nurses and pharmacists as prescribers may require amendments to provincial legislation expanding their scope of practice, and provincial regulatory colleges to work alongside professional associations to produce practice standards, educational tools and guidance documents *, there is precedent for this. In September 2020, BC's Provincial Health Officer issued a public health order* acknowledging that, in the context of dual public health emergencies of drug toxicity deaths and COVID-19, there are "*insufficient health human resources available to meet the needs of persons who use illegally produced and/or street procured drugs and who require pharmaceutical alternatives in order to mitigate the risks and harm of the dual public health emergencies."* The order authorized registered nurses and registered psychiatric nurses with additional educational preparation and experience to "*make a diagnosis of a problem substance use condition or substance use disorder"* and to "*prescribe specific drugs, including controlled substances, to manage or ameliorate the effects of substance use by a person who is diagnosed as having a problem substance use condition or substance use disorder" … "in the public interest to increase access to health professionals who can prescribe pharmaceutical alternatives to the toxic drug supply."* Following this order, in 2023, the BC College of Nurses and Midwives approved a series of new and amended standards*, limits, and conditions to create a designation of certified practice for registered nurses and registered psychiatric nurses.

Correspondingly, under provincial legislation, pharmacists are already permitted to prescribe in limited circumstances (for example, Ontario's *Regulated Health Professions Act*, 1991*), and some provinces have expanded pharmacists' prescribing powers in recent years*. In 2020, during the COVID-19 pandemic, Health Canada issued a temporary s. 56(1) class exemption *"in the public interest"* authorizing pharmacists to prescribe, sell or provide controlled substances in limited circumstances or transfer prescriptions. A 2021 survey * conducted by the Canadian Pharmacists Association found the majority of participating pharmacists are confident using the CDSA exemptions (71%) and believe the exemptions had a positive impact on patients (79%).

*Hospitals:*
The categorical exclusion of restricted drugs from the conduct of authorized activities in hospitals is unduly restrictive and may result in an imminent need to amend the CSR. Hospitals are some of the most controlled settings and the exclusion of activities with restricted drugs could prohibit hospital-based practitioners from implementing emerging promising practices in a controlled setting. While such activities are likely to be rare, we propose that there is no basis upon which to categorically exclude applications for licenses involving the use of restricted substances. Schedule 4 includes substances that may have promising utility in providing alternatives to the unregulated drug supply during treatment and novel application in addressing certain medical conditions. Notably, several of the listed "restricted" substances have a long history of use in various cultures. Thus, the prohibition on activities with restricted substances in hospitals does not provide appropriate pathways for hospitals to engage with potential patient-centered, culturally-informed care.

RECOMMENDATION:

- Ensure the CSR reflects the flexibility required for hospitals to fully engage with options for patient-centered, culturally-informed care.

*Minister:*
The CSR lacks sufficient safeguards to assess the accuracy, completeness, reliability and credibility of information that the Minister is required to consider in decision making and communications or to provide fairness and transparency. Rather than "authorizing" the Minister, the CSR mandates the Minister to refuse, revoke or suspend licenses based on criteria that do not align with comprehensive public health and safety analyses. Discretion, structure and expert advice are all required to support Ministerial decisions.

*Individuals:*
Provisions allowing for the import or export of a 90-day supply of prescription drugs for personal use are welcomed and should be considered as it relates to travel and prescribing within Canada to promote health care access to rural and remote communities, improve health equity, and support emergency response planning. While "carry limits" within Canada are not explicitly outlined in the CSR, the overwhelming focus on "diversion" presents significant barriers to prescribing adequately for people lacking easy access to a practitioner.

*Schedules:*
We are unable to comment on the Schedules within the timeline and character limits of this consultation. We welcome a future opportunity to do so.

*Additional Changes:*
*Prescribing of certain controlled substances by nurse practitioners:*
The Description notes that "Restrictions on prescribing opium and coca leaves are not needed since the practitioners can only prescribe marketed drugs." While we agree that restrictions under the NCPR should not be carried forward into the CSR, reliance on "marketed drugs" does not reflect Indigenous and culturally significant drugs that may have therapeutic value. Further, restricting pathways for prescribing non-marketed drugs does not align with the sustainable development goal of improving socioeconomic conditions for farmers (which should include coca and opium farmers). The CSR's limited focus on "marketed substances" reinforces reliance on for-profit, synthetic pharmaceuticals to the exclusion of plant-based substances that could be authorized through appropriate regulation in a manner that does not require that they be otherwise "marketed."

*Part J research authorization for restricted drugs:*
The non-inclusion of researchers in the CSR increases barriers to innovative research and novel medical interventions in controlled clinical settings. Drug control legislation often lags far behind contemporary evidence and so these exclusions will slow innovation and increase administrative burden. As noted in the Description, regulations applying to research are likely to

be developed in future. The consolidation and streamlining goals of the CSR, however, militate in favor of including researchers within the CSR.

**Regulatory Analysis (20,000)**

*Gender-based analysis plus:*
As we began to detail above, the CSR must consider that Black, Indigenous and other equity-denied people are grossly overrepresented in the criminal legal system and therefore more likely to carry drug-related criminal convictions resulting in exclusion from opportunities within the legal drug market under the proposed licensed dealer regulations. The proposed licensing requirements in the CSR maintain that any history of drug-related criminal convictions in the previous 10 years would necessitate an automatic refusal to grant, renew or amend a dealer's license in which an individual with a conviction is a senior person in charge, qualified person in charge or alternate qualified person in charge. This will effectively function as a system of exclusion for populations overrepresented in the criminal legal system. This outcome is wholly inconsistent with an appropriate gender based plus (GBA+) analysis and fails to incorporate the recommendation of the Expert Task Force to fully expunge criminal records from previous offenses related to simple possession. We elaborate on this below.

An analysis* published by the Public Prosecution Service of Canada reviewed possession and trafficking charges in 2017 in BC under Section 4(1) and 5(2) of the CDSA, which were the two most commonly charges laid in BC during this time. It assessed impact on various communities based on race/ethnicity/Indigeneity which clearly indicated that Indigenous people were grossly overrepresented in police arrests for drug-related charges. While several other racial groups including Black, White, Hispanic and West Asian people were heavily represented among those charged, it was racialized people who tended to be overrepresented in cases that proceeded to prosecution, indicating that white people were more likely to benefit from prosecutorial discretion and diversion. In the municipalities of Vancouver, Nelson and Duncan, Black and Indigenous people were overrepresented in drug-related charges by nearly 800%.

The connection between drug-related convictions and the overrepresentation of Black, Indigenous and other marginalized people in the criminal legal system is acknowledged by the federal government in its stated rationale for Bill C-5: An Act to amend the Criminal Code and the Controlled Drugs and Substances Act*, which removed mandatory minimum penalties and introduced a criminal record sequestration system after a two-year period for certain drug-related offences. Given that the federal government has recognized that addressing systemic inequities in the criminal legal system also requires a removal of certain drug-related convictions from an individual's criminal record, it should follow that the proposed CSR provisions for authorizing licensed dealers should, at a minimum, align with the two-year period under the sequestration system enacted in Bill C-5 rather than the ten-year period that is proposed, if these stipulations are to exist at all.

A GBA+ analysis should also ensure opportunities to participate in the legal market as licensed dealers and producers are guaranteed for individuals from equity-denied communities and groups

that have been most harmfully impacted by drug criminalization and its enforcement. Data from BC, Alberta and Ontario demonstrate that First Nations people in both regions are disproportionately harmed by the toxic unregulated drug supply, as detailed above (see: "regulatory development"). Further, Black people are distinctly overrepresented in drug-related criminal charges, which could then preclude the participation of Black people in the legal economy as licensed dealers under the proposed CSR. Data from Correctional Service of Canada showed that Black people comprised nearly half (45%) of all people incarcerated for import and export-related offences under Section 6 of the CDSA. An analysis submitted to the Ontario Human Rights Commission in 2020 which reviewed drug charges from 2013-2017 (prior to the legalization of cannabis in 2018) in Toronto, Ontario found that Black people were 4.3 times more likely to be charged for cannabis possession and 3.2 times more likely to be charged for non-cannabis drug possession. Further, Black men were 8.7 times more likely to receive a cannabis possession charge and 6.4 times more likely to receive a non-cannabis drug possession charge.

Considering the evolving nature of drug policy and the unregulated drug toxicity crisis in Canada, as well as emerging scientific research around therapeutic uses of substances such as psilocybin and MDMA, it is reasonably probable that the legal economy may expand. Targeted equity-centered initiatives under the CSR for granting dealer's licenses should be incorporated to partially address historic and ongoing racial inequities related to drug criminalization and economic opportunities within the legal drug market. There is precedent for targeted equity-based initiatives in the legal drug market. In New York state, 50% of all licenses for cannabis cultivation, processing, distribution and retail must be granted to those in a targeted social and economic equity program which includes communities disproportionately impacted by cannabis prohibition, women, racialized people, distressed farmers, service-disabled veterans, low-income individuals, and those with a cannabis-related conviction prior to legalization either themselves or within their immediate family. Similarly, the state of Missouri determines eligibility for its cannabis microbusiness licensing that includes consideration of low-income levels, disability, history of arrest, prosecution or conviction of cannabis-related offence, demographic information related to location including poverty levels, cannabis-related incarceration rates and unemployment rates.

An appropriate GBA+ incorporated into the CSR would include targeted initiatives to ensure participation by women, gender-diverse people, Black, Indigenous and racialized people, and those with a history of certain drug-related convictions to participate in the legal economy as licensed dealers.

RECOMMENDATIONS:

- Ensure an appropriate GBA+ analysis is conducted, including assessing the impacts of disproportionate drug-related arrests and convictions for Indigenous and Black communities on the eligibility stipulations related to criminal records for licensing and other relevant roles.

- Ensure that the criminal record history requirement for licensing, at a minimum, aligns with the two-year sequestration period enacted under Bill C-5 and is no greater than two years. Consider removing the criminal record history requirement for eligibility.

- Introduce measures that are designed to ensure participation by Indigenous peoples and equity-denied communities in the legal market, including as licensed dealers.

*Cost-Benefit analysis**:***

We are unable to provide comprehensive feedback on the economic cost/benefit analysis outlined. We note briefly that the analysis does not consider the direct costs of enforcement activities related to the criminalized unregulated supply (including policing, courts and incarceration), nor does it include indirect costs related to the down-stream medical and social consequences of enforcement (including housing and employment insecurity, emergency overdose response, and overall healthcare burden) – both of which are implicated in determining how restrictively the CSR is framed. The more restrictive the CSR provisions are, the more likely the CSR is to contribute to the above costs. The CSR likewise overlooks the potential benefits of improving pathways of access to regulated substances and does not include the potential benefits of equity-focused economic opportunities for equity-denied groups.

RECOMMENDATIONS:

- Update the cost/benefit analysis to include the direct and indirect costs of the current unregulated drug crisis and CDSA enforcement. Outline the economic benefits that would accrue if the CSR were amended appropriately to mitigate some of these costs and to provide expanded economic opportunities within the licensing system.

- Include an analysis of the costs associated with barriers to accessing currently restricted substances in order to conduct clinical studies to determine therapeutic value of currently restricted substances.

*Strategic environmental assessment:*

While we agree that a strategic environmental assessment is likely not required per the Cabinet Directive, the development of the CSR has not duly considered the environmental impacts of the CSR in "producing" nations. The limitations in the CSR related to licensed pathways for producers, largely preclude the possibility of accommodating bilateral, not-for-profit agreements with farmers of plant-based psychoactive substances in the global south, thus the CSR contributes to ongoing environmental degradation in these regions.

**Implementation, compliance and enforcement, service standards section (20,000)**

This section describes the CSR's compliance goals without appropriate consideration of public health needs. The description states, in part "*In instances of non-compliance, consideration is given to factors such as the nature of the alleged violation, effectiveness in achieving compliance with the CDSA or the Cannabis Act and their regulations, and consistency in enforcement when deciding which enforcement measures to take.*" This fails to address key public health considerations that are necessary in making determinations that will produce improved and equitable public health and safety outcomes.

In addition to this, moving from a failed criminal enforcement model to a cohesive public health regulatory model requires reconsideration of Health Canada's decision that the CSR would not "change in the manner in which regulations are enforced under the CDSA." Expertise in the oversight and enforcement of the CSR, decreasing interactions with police and the criminal legal system, and ensuring rights of review are essential.

RECOMMENDATIONS:

To increase regulatory consistency and better safeguard the public health aims of the CSR, create a separate oversight system such as that which is provided for in the Food and Drug Act adding the following provisions to the CSR:

- Add: "For the purposes of the administration and enforcement of this Regulation, the Minister may designate individuals or classes of individuals, who are not peace officers, as inspectors to exercise powers or perform duties or functions in relation to any matter referred to in the designation."

- Add: "Designated individuals or classes of individuals must, at a minimum, have specialized knowledge and training in public health, the risks posed by the unregulated drug supply, and the practicalities of the operations of licensees and practitioners."

- Add: "Authorized people under the CSR and other directly impacted individuals, have a right to receive disclosure of information gathered by designated individuals, to make submissions, and to appeal a decision made by a designated individual."

**Proposed regulatory text section (20,000)**

The notice period of 60 days to provide input is insufficient and shorter than other currently posted consultation periods, some of which provide up to 90 days for comment. Given the length of the CSR, the complexity of the issues arising and the potential unintended consequences of certain aspects of the CSR as drafted, 60 days is not an adequate notice period for comment.

While we have endeavored to provide helpful input, our ability to comment fully on the text of the CSR has been limited within the time provided. We request the opportunity to provide further input on the issues we have identified and the recommendations we have proposed during the next phase of the CSR review process.

Additionally, the 20,000 character limit to provide feedback under “licensed dealers” is inadequate to address the lengthy and complex provisions included therein.

**Controlled substances regulations (20,000) - No comment**

**Interpretation (20,000)**

RECOMMENDATIONS:

- Amend "international obligation" to "means an obligation relative to a controlled substance set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres, including international human rights instruments and relevant environmental and sustainable development agreements" and define "contravene an international obligation" accordingly.

- Amend "prescription" to remove "other than a restricted substance" and to read, in full: "an authorization given by a practitioner that a stated amount of a controlled substance be sold or provided for the individual named or the animal identified in it, or for delegated authorizations allowing the dispensation of a controlled substance to an individual or a class of individuals with identified health conditions."

- Amend "practitioners" to include a non-exhaustive list of other regulated professionals such as nurses and pharmacists.

- Add definitions for "public health" and "public safety" that incorporate the principles and goals outlined in our submission (see General Comment, Issues, Background, Regulatory Development, Regulatory Analysis, and Description of "Licensed Dealers") and define "risks to public health and safety" accordingly, including the provision of a rationale for the definitions that is grounded in contemporary scientific evidence and not reliant on "risk of diversion" as the sole criteria for evaluating risks to public safety.

- Add a definition for "equity-focused licensing and access" including "means that licensing decisions and other initiatives under the CSR must consider the promotion of economic opportunities and support improved access to alternatives to the unregulated and illegal drug supply for equity-denied communities".

- Add a definition for "emergency access" including "means authorized access to licenses and substances regulated under the CSR that may be granted on an expedited basis and which may include authorized access models outside of the definition of "prescription" to meet urgent community health and safety needs".

**General section (20,000) – No comment**

**Possession (20,000)**

RECOMMENDATIONS:

- Amend s5(1) to "... is authorized to possess one or more of the following controlled substances" to provide for more streamlined authorizations that allow for the possession of more than one substance in a single authorization to properly accommodate licensee, practitioner and authorized individuals' need to possess multiple substances to adequately address poly-substance use and decrease the burden on people seeking licenses/authorizations.

- Amend s5(2)(e)(i) to include "has obtained the controlled substance in accordance with a prescription or emergency access authorization that was issued or obtained in accordance with these Regulations from one of the following persons for their own use, for the use of another individual or for an animal: (A) a practitioner, (B) a pharmacist, or (C) a person authorized by way of emergency access.

- Add s5(2)(f) "a provincially or federally incorporated not for profit entity whose mission is to sell or provide controlled substance(s), and (i) whose activities are conducted for the sole benefit of the entity's membership to improve member health and safety; (ii) whose activities are conducted on a not-for-profit basis; and (iii) whose membership is comprised of people seeking to obtain a controlled substance(s) in accordance with these Regulations for their own use."

- Amend s5(4) to remove "other than a restricted drug." Whether and how a restricted drug can be possessed for the purpose of export by an individual defined in s190 (exporting a drug for personal use) can be dealt with appropriately through the authorization process without need to unduly restrict potentially beneficial activities through a full prohibition on restricted drugs.

- Amend s6(1)(b) to remove "other than one who is practicing in a hospital".

- Amend s5(2) and 6(1) adding (g) "a person authorized under emergency access provisions" and amend 6(1)(f) to include "... from a practitioner or authorized "emergency access" provider...".

- Amend s5(1) and 6(1) to include "qualified researcher and affiliated research staff" as a category of "authorized persons".

**Licensed Dealers (20,000)**

Flowing from the analysis above under "Description", our recommended amendments themes pertain to of precision, accuracy and transparency in defining "public safety" and "risks to public health and safety"; informed, transparent and flexible public health and safety decision making; and promotion of equity, accessibility and innovation.

We recommend amending the language regarding Ministerial directives to afford flexibility for context-specific decision-making. There are many scenarios wherein a risk to public safety would need to be balanced with other public health and safety risks. As just one example, Canada will continue to experience natural disasters and extreme weather events (e.g., wildfires, severe storms), some of which will require the evacuation of entire communities, with many residents abruptly losing access to their healthcare providers. In such circumstances, practitioners under the CSR would be required to choose between prescribing larger doses of controlled substances to patients who are displaced and risk losing their licenses because a Minister has "reasonable grounds to believe" the prescriptions could be diverted, or to decline to meet a patients' medical needs to retain their license. Neither healthcare providers nor people in receipt of such prescriptions should ever be put in this position.

Relatedly, this section of the CSR fails to clearly define the term "reasonable grounds to believe." To the extent that this term may be derived from criminal law principles of interpretation, we suggest that a criminal-legal framework for drafting and interpreting the CSR is inappropriate. Rather, a framework that balances public health and intersectoral public safety is required. We thus strongly caution against the usage of the term "reasonable grounds to believe" given the breadth of criminal-legal understandings that will inform the interpretation of this language to the exclusion of public health analytical factors. However, in the alternative we propose that the CSR include criteria for what constitutes "reasonable grounds," that clearly delineate how sources of information will be evaluated for accuracy, completeness, reliability and credibility. Governance at the intersection of public health requires that stigma and misinformation be interrogated and challenged not only in public discourse, but in legislation. To that end, the CSR must include proper safeguards and oversight to ensure that harms are not produced if claims that could lead to refusal, suspension, or revocation of a license are not grounded in scientific evidence and reliable data.

In the same vein, while police information and public statements are generally accepted as neutral and accurate, law enforcement entities have contributed to the propagation of misinformation about drugs. We do not intend to imply this is intentional, merely that it occurs. Examples include: the 2012 "Miami zombie case"*, wherein police reported that "bath salts" were involved in an attack on a homeless person but toxicology later showed the person only had THC (cannabis) in their system; numerous (and persistent) instances of police across North America claiming they overdosed from fentanyl exposure* – claims that have been disproven multiple times; and, in 2023, police in Belleville, Ontario* incorrectly claiming that opioids were contaminated with gamma hydroxybutyrate (GHB). This claim was not substantiated in the drug analysis data but was not publicly retracted. Information that is inaccurate or speculative can

work against public health goals because it creates confusion among people who use drugs and service providers, stigmatizes people who use drugs, and lends to poor policies developed on faulty assumptions or evidence. We therefore recommend removing "peace officers" as a source of information guiding Ministerial decisions.

Without precise language about how Ministers are to evaluate the information they receive, and when combined with the directive that a Minister "must" or "must not" complete a course of action, we foresee this section of the CSR being vulnerable to misinterpretation; inadequate to provide for transparent, methodical and reasonable administrative decision making; and creating problematic limitations on discretion that could produce harms to public health.

The licensing scheme mandates that a Minister complete or not complete various courses of action in accordance with Canada's "international obligations". As we detail above (see "Issues"), Canada's international human rights commitments may be contraindicated by strict textual adherence to UN Drug Control Conventions to the exclusion of international human rights obligations. In addition to domestic concerns, refusing a license for a domestic applicant could have indirect, deleterious consequences for Indigenous, peasant, farmer, and rural communities in the developing world due to the transnational nature of illegal drug markets (see "Description" of licensed dealers above). The tension between upholding UN Drug Control Conventions and meeting Canada's human rights obligations raises several questions about how a Minister will be expected to make decisions about licensing. The CSR should clearly outline how these dual obligations will be considered and prioritized.

Given the implications of decisions that may be made under the CSR, the subject matter expertise required to identify and balance the public health, human rights and safety issues that may arise, and the need to interrogate structural stigma within decision making on these issues, we recommend that the CSR mandate the creation of an expert council to review both information that may contribute to a decision to issue, refuse, revoke, amend or suspend a license and to advise on questions of adherence to international obligations. Such a council need be independent, non-partisan and, at a minimum, include members with: lived experience of harm related to the unregulated drug supply and of being a patient impacted by the activities of licensees and practitioners under the CSR; public health and public policy expertise; human rights and international drug control expertise; experience as a licensee; experience as a practitioner.

RECOMMENDATIONS, GENERAL:

- Decision making: Create a rubric for Ministerial decision making that is publicly available; and add provisions before the existing s7 to establish an expert advisory council to evaluate information and international obligations and to provide recommendations to the Minister.

- Emergency access: Add provisions before the existing s7 to establish an "emergency access" process that aligns with the proposed definition of "emergency access" and

details an expedited process by which an authorized person may possess, produce, import and distribute designated substances to authorized individuals to meet urgent community needs, including need to ensure equitable access and support for rural/remote communities and displaced communities; amend s5(1), 6(1)(noted above) and provisions related to "emergency supply" accordingly. This process should be included in the CSR rather than the s56 process under the CDSA to ensure timely and responsive access, given the urgency of needs that arise and the established record of requests for such access, see "Issues" and "Background".

- Equitable outcomes: Add provisions before the existing s7 to establish a process for issuing and renewing licenses to promote equitable access to licensing opportunities as outlined above under "Regulatory Analysis" and "Regulatory Development" including mandatory prioritization of licenses to equity-denied communities, and exceptions to ineligibility provisions for persons qualified for consideration under the "equitable access" provisions; update to s9(4), 14(2)(c), 18(2)(c), 22(2)(c) to include "the applicant is a member of an equity-denied community and eligible for consideration under the "equitable access" provisions".

RECOMMENDATIONS, SPECIFIC PROVISIONS:

The following pinpoint recommendations cover sections 7 to 33 in detail. Given the repetitive nature of the CSR and character limits for feedback, we have not identified every subsequent section where the same recommendations apply. We trust that the following provides adequate detail as to the recommendations we propose be adopted throughout:

- Criminal records: Remove s10 or amend to align with the record sequestration provisions outlined in Bill C-5 and review/amend ss10(2), 11(2)(c) and (d), 14, 18, 22, 25, 33 to limit inequitable exclusion of equity-denied communities accordingly.

- Authorized persons: Amend s9(3) to ensure researchers and affiliated university staff are eligible for licensing to conduct clinical trials and other program evaluations.

- Agreements for non-marketed plant-based substances: to allow for licensing that integrates bilateral agreements with producers of non-marketed plant-based substances focused on equitable and sustainable scientific, medical and research opportunities in partnership with farmers and others in the global south, amend s11(f), (g), and remove s14(1)(e), 18(1)(e), 22(1)(d) or amend to include "other than for scientific or medicinal purposes".

- International obligations: amend ss12(1)(h)(i), 16(2)(a), 20(2)(a), 24(2)(a), 30(1)(b), 35(1)(e) to "ensure that international obligations, including international human rights standards, are respected"; amend ss14(1) (d), 18(1)(d), 22(1)(c) to "an activity for which the license requested does not align with international obligations, taking into consideration international human rights obligations"; remove s37(1)(b); amend

ss14(1)(j), 18(1)(j) removing "or has been involved in an activity that contravenes an international obligation". The removal of "international obligation" in t ss14(1)(j), 18(1)(j) is recommended because these are obligations on the state, not individual licensees.

- Multiple substance licensing: Clarify ss10, 11, 12 to ensure licenses can be granted for multiple substances in one license application.

- Public safety: Remove from ss12(1) (h)(iii), 14(1)(k), 16(2)(c), 18(1)(k), 20(1)(c), 22(1)(i), 24(2)(c), 25(1)(d), 30(1)(d), 35(1)(e)(ii), (g) "including the risk that a controlled substance could be diverted to an illicit market or use"; and ss14(2), 22(2), 25(2), 30(3), 32(1), 32(2) "including to prevent a controlled substance from being diverted to an illicit market or use"; and amend ss14(1)(j), 16(1)(j) to remove "has been involved in the diversion of a controlled substance to an illicit market or use" and replace with "has been involved in an activity that is likely to negatively impact public health and safety as defined herein and which is not justifiable based on any potential benefit to public health or safety". As outlined extensively "diversion" is an inappropriate and limiting focus for assessing public safety and licensing decisions should not be made based solely on this. Diversion, while not the norm, can occur in nearly any medical context. Licensing decisions must be addressed based on comprehensive and factual understandings of risks to public safety and in the context of broader public health considerations.

- Discretion to balance diverse public health and safety goals: amend ss14(1), 18(1), 22(1), 25(1), 32(1), 33(1), 37(1), 40(1), 41(1), 45(1), 48(1), 49(1) removing "Minister must" and adding "Minister may".

- Rigor of record of decision: amend ss14(1)(i), (j), (k), 14(2), 18(1)(i), (j), (k), 22(1)(h), (i) to remove "reasonable grounds to believe" and replace with specific factors that will be considered in assessing the comprehensiveness, accuracy, reliability and credibility of information; remove from ss14(1)(j), 18(1)(j), 33(1)(h) "peace officer" or amend to read "where an information has been laid in relation to a criminal investigation".

- Informed decision making: amend ss12, 14, 16, 18, 20, 22, 24, 25, 30, 32, 33, 35, 37, 40, 41, 43, 45, 48, 49 to include "…on advice and recommendation of the expert advisory council, the Minister…"

- Procedural fairness: amend ss14(3), 18(3), 22(3) to "Prior to rendering a decision refusing to issue(renew or amend, or before revoking – as applicable) a license, the Minister must consider the recommendations of the expert advisory council and intersectoral health, safety and human rights factors and provide the applicant with an opportunity to be heard"; amend ss32(2) (and as applicable, s33(3)), to "Except in exigent circumstances, prior to suspending a license, the Minister will: (a) consider the recommendations of the expert council, intersectoral health, safety and human rights factors; (b) provide the applicant notice setting out the authorized activity(ies) and

controlled substance(s) that may be suspended and the corrective measures that must be carried out and the date by which they must be carried out; and (c) provide the licensee an opportunity to be heard; add 32(2.1) “If the Minister, based on this assessment, determines that a license is to be suspended, the suspension takes effect as soon as the Minister provides the licensed dealer with a written notice that: (a) sets out the authorized activity(ies) and controlled substance(s) that are the subject of the suspension, as well as the reasons for the suspension; and (b) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.”

See above for the content of further recommendations applicable to ss 34-49.

- Supporting health care access and innovation: amend s50(a)-(d) and s60 to read “one or more controlled substances”; remove from (b)(iv) “with the exception of a restricted drug”; amend (b)(v) to read “a person or class of persons exempted under subsection 56(1) of the Act with respect to the controlled substance(s), if the terms and conditions for the sale or provision by a licensed dealer(s) are specified in the exemption"; remove from ss56(1) “other than a restricted drug”; add ss56(2)(c) “they have received confirmation from the Minister that any request to sell or provide a restricted drug for purposes other than destruction is accurate and valid”; amend s58(2)(a) to “the licensed dealer first receives and reviews a letter of authorization to ensure compliance with any criteria or conditions applicable to a licensed dealer” and add (d) “the licensed dealer has confirmed that the order outlined in the authorization has not been duplicated by another licensed dealer”; amend s60 by removing “by the licensed dealer”. These amendments are required to safeguard against abusive practices, monopolies and unnecessary administration under the CSR should a practitioner or authorized person have good reason to change licensed dealers or be authorized to access multiple substances from one or more licensed dealers to ensure that authorizations can be fulfilled.

**Pharmacists (20,000)**

Restrictions on pharmacist activities with restricted substances can be adequately managed through authorizations under the CSR and provincial regulatory bodies, the exclusion of restricted substances provided for in the draft are unnecessary and may lead to further need to amend the CSR. Other recommendations are proposed to promote efficient and accessible practice.

RECOMMENDATIONS:

- Amend ss91(1), 92(1), 92(2), 93(1), 94, 95, 98(1) to remove “other than a restricted drug” and remove s91(2).

- Amend s95 to read “to a person or class of persons exempted under…”

- Amend s98(1)(a) to “in the case of an individual, a written prescription or verbal prescription that is verified with the prescriber and the prescriber’s identity is confirmed.”

**Practitioners (20,000)**

Restrictions on practitioner activities with restricted substances can be adequately managed through authorizations under the CSR and provincial regulatory bodies, the exclusion of restricted substances provided for in the draft are unnecessary and may lead to further need to amend the CSR. Other recommendations are proposed to promote efficient and accessible practice.

RECOMMENDATIONS:

As per the above recommendation, we recommend amending the definition of "prescription" to authorize delegations allowing the dispensation of a controlled substance to an individual or a class of individuals with identified health conditions. S. 123 should be correspondingly amended to allow such delegation as follows:

- S123.1: "A practitioner may delegate authorization to dispense a prescribed controlled substance to an individual or a class of individuals with identified health conditions if: (a)(i) the authorized delegate falls within a class of individuals authorized under provincial regulation; or (a)(ii) is the designated person in charge of an incorporated entity defined in s 5(2)(f); and (b) the delegation is completed in writing and submitted to the relevant provincial regulatory body, if required."

- Amend s126(1) to remove "other than a restricted drug" and add "…to an individual or authorized incorporated entity for their own use, for the use of members of the incorporated entity or for…"; remove (2) (only if the amendments to 126(1) are also accepted).

- Amend s128(1) to remove "of medicine" and remove s128(1)(a) (limiting oversight of emergency supply to a "practitioner of medicine" could unduly restrict emergency response planning and prohibition on the inclusion of restricted drugs would increase the risk of overdose for people navigating emergency circumstances).

**Hospitals (20,000)**

RECOMMENDATIONS:

- Remove s151 “Non-application – restricted drugs” and amend all references to “in the case of a controlled substance set out in any of Schedules 1 to 3” accordingly.

- Amend s152 adding “(c) the person is a researcher or authorized research assistant approved by the hospital to conduct research or evaluation.”

- Amend s156(1) to read “A hospital may sell or provide a controlled substance to a practitioner or authorized emergency access provider, other than one who is practising in a hospital,...”; amend ss156(1)(b), (b)(i) and (b)(vi), 156(2) to add “...or authorized emergency access provider...”; amend s156(1)(iv) to read “the name, form and quantity of the controlled substance”.

- Add s156.1:

    - 156.1 (1) A hospital may sell or provide a controlled substance to researcher authorized by the hospital to conduct research or evaluation, if
      (a) the sale or provision is required to pursue the research or evaluation; and
      (b) the hospital first receives from the researcher either a written order that is signed and dated and that contains the following information or a verbal order:
      (i) with respect to the researcher, their name and the name and municipal address of their affiliated institution,
      (ii) with respect to the hospital, its name and municipal address,
      (iii) the date of the order,
      (iv) the name, form and quantity of the controlled substance,
      (v) in the case of a finished product, (A) its name or, if applicable, its brand name, (B) its form, strength and quantity, and (C) its drug identification number, if any, and
      (vi) a copy of the researcher’s ethics approval for the proposed research or evaluation.
      Exception — prohibition
      (2) A hospital must not sell or provide to the researcher a controlled substance that is not included in the ethics approval for the research.

- Amend s159 to read “A hospital may sell or provide a controlled substance to an individual or the designated person in charge of an incorporated entity authorized under s5(2)(f) if (a) the sale or provision is for the individual’s own use, for the use of another individual, an authorized class of individuals or for an animal; and (b) a practitioner first issues a written or verbal prescription for the individual or authorized class of individuals for whom or animal for which the controlled substance is sold or provided.”

- Amend s171 to read “Substances sold or administered – individuals, authorized entities, researchers : A hospital that sells or provides a controlled substance to an individual, a designated person in charge of an incorporated entity or a researcher for their own use, for the use of another individual or authorized class of individuals or for an animal or for research or evaluation purposes, or that administers a controlled substance to an individual or an animal, must record the following information:

    (a) the name of the person selling, providing or administering the controlled substance;
    (b) the name of the individual who is named in the prescription or who is responsible for the authorized entity, research, evaluation or animal identified in the prescription and, if applicable, the name of the animal;
    (c) the date of the sale, provision or administration;
    (d) the name, form and quantity of the controlled substance; and
    (e) in the case of a finished product,
        (i) its name or, if applicable, its brand name,
        (ii) its form, strength and quantity, and
        (iii) its drug identification number, if any.

**Minister (20,000)**

The provisions herein reflect one of our fundamental concerns with the CSR. While language in the above provisions is mandatory in relation to downwards action (refusal, revocation, suspension of licenses) to ensure "compliance" with international obligations (in some sections even going to far as to place a burden on individuals to ensure the fulfillment of those obligations), the language in s184 is discretionary in relation to Canada's reporting to the INCB related to fulfillment of those same obligations. This exemplifies an inequal balancing of authority and discretion to the detriment of people seeking to conduct activities under the CSR and illustrates the ability – and necessity – of the CSR to ensure informed and transparent discretionary decision making.

As outlined above, decisions impacting the rights of licensed dealers, authorized people and those who could be negatively impacted by a Minister's decision must be thoughtfully considered, and public health and human rights concerns must be taken into account.

Our recommendations herein will focus on ensuring that Ministerial decisions and communications are evidence-informed, accurate, reliable and complete and that a framework is established to guide Ministerial decision making.

RECOMMENDATIONS:

- Amend s182 "The Minister must provide in writing any factual information that has been obtained under the Act or these Regulations, once it has been reviewed by the expert advisory council and the Minister to ensure its accuracy, completeness, credibility and reliability..."; and s182(a)(ii)(c) "contravened these Regulations in a manner that falls within the provincial authority's mandate".

- Amend s184 to read "The Minister may provide to the International Narcotics Control Board any information that is obtained under the Act or these Regulations, once it has been reviewed by the expert advisory council and the Minister to ensure its accuracy, completeness, credibility and reliability, if the provision is necessary to enable Canada to fulfill its international obligations in relation to controlled substances, taking into consideration Canada's obligations under human rights treaties."

- Amend s185 to read "The Minister may, for the purposes of the administration or enforcement of the Act or these Regulations or if it is necessary to enable Canada to fulfill its international obligations in relation to controlled substances and human rights, provide to a competent authority..."

**Individuals (20,000)**

RECOMMENDATIONS:

- Amend s187 to read "An individual who has obtained, in accordance with the Act and its regulations, a controlled substance specified in a prescription for another individual or authorized class of individuals named in that prescription or authorization may deliver, transport, sell or provide the substance to that individual or class of individuals."

- Amend s189 to read "On entering Canada, an individual may import a substance containing a controlled substance that is in their actual possession or that forms part of their baggage if..."; add s189(a)(iv) "if the individual is the designated responsible person of an authorized incorporated entity and the types and amounts of substances imported are those that have been authorized for sale or provision to an authorized class of individuals who are members of an authorized incorporated entity;" amend s189(c)(i) "the name or names of the individual or class of individuals for whom or animal for which the substance was lawfully obtained"; s189(c)(ii) "the name of the medical professional or other authorized practitioner who authorized the substance to be obtained"; s189(c)(iv) "the daily dose of the substance authorized by the medical professional or other authorized practitioner".

- Amend s190 to read "On departing Canada, an individual may export a controlled substance that is in their actual possession or that forms part of their baggage if..."; add s190(a)(iv) "if the individual is the designated responsible person of an authorized incorporated entity and the types and amounts of substances exported are those that have been authorized for sale or provision to an authorized class of individuals who are members of an authorized incorporated entity"; amend s190(b)(i) "the name or names of the individual or class of individuals for whom or animal for which the substance was lawfully obtained"; s190(b)(ii) "the name of the medical professional or other authorized practitioner who authorized the substance to be obtained"; s189(b)(iv) "the daily dose of the substance authorized by the medical professional or other authorized practitioner".

**Test kits (20,000) – No Comment**

**Miscellaneous Provisions (20,000)**

*Advertising:*
As outlined above, a significant contributing factor to the current unregulated drug crisis is the advertisement and promotion of marketed, for-profit pharmaceuticals – and the subsequent mass de-prescribing of people who had been prescribed those pharmaceuticals. We therefore recommend that Health Canada refine provisions authorizing the advertisement of controlled substances to limit potential negative impacts of such advertising in alignment with a comprehensive definition of public health and safety principles.

RECOMMENDATION:

- Consider limitations on the advertisement of controlled substances to children and youth.

- Consider and, as appropriate, incorporate restrictions on advertising contained in tobacco product legislation.

- Require that for-profit pharmaceutical companies and any person who advertises certain controlled substances (to be determined by Health Canada) on their behalf register those advertisements with Health Canada including the content, audience, expenditures on advertising, and any promotions, discounts or other incentives offered.

*Other:*
Under "miscellaneous" we recommend addressing certain key recommendations in more detail including:

*Ministerial decision making:*
Outline the public health and safety factors that will inform Ministerial decision making and communications including: the prioritization of public and individual health; the incorporation of intersectoral public safety considerations (as outlined in this submission and not reliant or premised upon diversion as the sole or central consideration); advancing health, economic, social and environmental equity and human rights; decreasing policing and criminal law involvement in equity-denied communities; promoting access to essential medicines; upholding Indigenous self-determination; interrogating misinformation and stigma within the interpretation, application and enforcement of the CSR.

Create a rubric for Ministerial decision making that includes how the Minister will assess the accuracy, completeness, reliability and credibility of information; how the Minister will assess and balance information received and the advice of the expert advisory council; and how the above public health and safety factors will be incorporated into Ministerial decision making.

*Expert advisory council:*
Delineate the composition, mandate, terms, authorities and accountabilities of an expert advisory council to review information received under the CSR, to provide the Minister with

recommendations for decision making and communications, and to assess international and domestic human rights obligations.

*Enforcement:*
Delineate the composition, mandate, terms, authorities and accountabilities of a separate enforcement body as detailed above under "Implementation, compliance and enforcement, service standards" including the addition of the following provisions:

- #(1) For the purposes of the administration and enforcement of this Regulation, the Minister may designate individuals or classes of individuals, who are not peace officers, as inspectors to exercise powers or perform duties or functions in relation to any matter referred to in the designation.

- #(2) Designated individuals or classes of individuals must, at a minimum, have specialized knowledge and training in public health, the risks posed by the unregulated drug supply, and the practicalities of the operations of licensees and practitioners.

- #(3) Authorized people under the CSR and other directly impacted individuals have a right to receive disclosure of information gathered by designated individuals, to make submissions, and to appeal a decision made by a designated individual.

*Equity:*
Delineate the communities, processes, and opportunities that will proactively seek to engage disproportionately harmed and criminalized communities in the licensing scheme under the CSR and designate a steering committee of community members to guide this process.

**Repeals (20,000) – No Comment**

**Coming into Force (20,000) – No Comment**

**Schedule 1 (20,000)**

As noted above, we are unable to comment on the Schedules within the timelines and restriction of this consultation process.

We note briefly, as outlined in the Issues section, the scheduling of coca leaf has been problematized and contested at the international level and described as "*a grave historical error with severe social impacts and infringements on indigenous and cultural rights"*. Its status as a narcotic under the proposed CSR undermines the cultural significance of coca leaf to Indigenous communities internationally and represents a lack of awareness and leadership from Canada related to Indigenous rights and the preservation of Indigenous cultures. Given the ongoing study of coca leaf and enduring debate regarding its status as a scheduled substance, as well as the

opportunity to improve health and social outcomes for global Indigenous communities, we recommend that coca leaf be removed from Schedule I.

**Schedule 2 - No Comment**

**Schedule 3 - No Comment**

**Part 1- No Comment**

**Part 2 - No Comment**

**Schedule 4 - No Comment**

**Confidential business information - No Comment**