An Overview to the APMPR, PER and proposed amendments to the FDR.

The APMPR are regulations under the CDSA. The PER are regulations under the CDSA and the FDA. No amendments to any act of parliament are necessary for these proposed regulations. The APMPR, the PER and the amendments to the FDR will create a system that can predictably provide predictable, quality-controlled products to Canadians for therapeutic purposes based on a medical document executed by a healthcare practitioner. The bases upon which healthcare practitioners can write medical documents would be regulated at the provincial level by colleges and other healthcare regulators. Health Canada has experience regulating access to medical cannabis from 2001 to 2018 under the CDSA, and since 2018 under the *Cannabis Act*.[1] Similarities between the structure of the APMPR and the structure of the *Cannabis Regulations*,[2] (the "**CR**") allow for efficiencies from Health Canada's experience regulating cannabis generally, and in particular regulating cannabis licensing, cannabis products and access to cannabis for medical purposes.

Additional details are below. We invite dialogue on the contents of this letter, the PMPR, the PER and the proposed amendments to the FDR.

Subsection 56(1) Exemptions and Uncertainty

Subsection 56(1) exemptions are typically issued for research. The exemptions issued for patients needing psilocybin each allow a particular individual to possess psilocybin for therapeutic use in relation to end-of-life depression or other conditions.

The subsection 56(1) exemptions issued to patients and healthcare practitioners to date did not define an authorized source of psilocybin. As a result, these Canadian do not have access to a well-defined source of quality-controlled psilocybin material with clear labelling for the amounts of psilocin and psilocybin present in the psilocybin material. The lack of a well-defined source of psilocybin in these particular examples illustrates shortcomings of issuing ad hoc authorizations to possess through CDSA exemptions.

[1] SC 2018 c 16
[2] SOR/2018-144

The subsection 56(1) exemptions issued to patients and healthcare practitioners to date, as with all subsection 56(1) exemptions, are at the discretion of the Minister of Health. The result is that a government agency is making health care decisions for individuals, rather than the individual's healthcare practitioner. The lack of predictability as to whether a healthcare practitioner can provide access, and the absence of federal authorizations under the CDSA to provide context to colleges and other provincial regulators illustrates shortcomings of issuing ad hoc authorizations to possess through CDSA exemptions. Regulated medical access to quality-controlled psilocybin products that is provided through a medical document would address these shortcomings.

Like medical use of psilocybin, medical use of cannabis involves use of a substance that is not a drug product carrying a drug identification number, and that is regulated for commercial production and sale under the Part C of the FDR. This important common feature makes medical use of cannabis a good comparator to medical use of psilocybin. Medical access to cannabis is regulated under the CR. Medical access to cannabis is through a medical document that a healthcare practitioner writes for their patient. No subjective approval from Health Canada or any government agency is required for a medical document to provide access under the APMPR. Cannabis product requirements and restrictions, including packaging and labelling, can also be productively applied to psilocybin products similarly to the CR, and the APMPR take this approach.

Conclusion

For at least the reasons in this letter, if ad hoc subsection 56(1) exemptions authorizing possession of psilocybin without a regulated source continue to be issued to Canadians, it is possible that the scope of different exemptions will vary and that the criteria for issuing exemptions will be inconsistent, resulting in confusion by patients, health care practitioners and law enforcement. It is also possible that unsafe material will be sourced by those Canadians. The current ad hoc system cannot be effectively scaled and will inevitably fail, with potentially tragic consequences. The system proposed through our draft APMPR, PER and amendments to the FDR address these shortcomings in a way that can be implemented cost-effectively by leveraging Health Canada's experience regulating cannabis.

As above, we invite dialogue on the contents of this letter, the PMPR, the PER and the proposed amendments to the FDR.

Thank you.