

Review of Controlled Drugs and Substances Act

Canadian Medical Association:
Submission to Health Canada in response to the
consultation on the Controlled Drugs and
Substances Act and its regulations

March 17, 2014



A healthy population and a vibrant medical profession
Une population en santé et une profession médicale
dynamique

The Canadian Medical Association (CMA) is the national voice of Canadian physicians.

Founded in 1867, the CMA is a voluntary professional organization representing more than 80,000 of Canada's physicians and comprising 12 provincial and territorial medical associations and 60 national medical organizations.

CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.



Introduction

The Canadian Medical Association (CMA) is pleased to provide this brief in response to Health Canada's consultation on the *Controlled Drugs and Substances Act (CDSA)* "regarding any challenges, gaps or suggested improvements."

The CMA welcomes the consultation and review of the *CDSA* and its associated regulations. This is an important legislative framework with direct implications for public health, quality care and patient safety.

The CMA's recommendations outlined in this brief aim to establish new measures and mechanisms under the *CDSA* that would contribute to improved public health and patient safety. The CMA looks forward to the opportunity to discuss these issues in greater detail with Health Canada as this consultation proceeds.

Part 1: Supporting a Regulatory Approach that Advances Public Health, Quality Care and Patient Safety

As an overarching principle, it is the CMA's position that the modernization of the *CDSA* legislative and regulatory framework should be guided first and foremost by the objective of improving public health, promoting quality care and enhancing patient safety.

In enacting the *CDSA* and promulgating its regulations, enforcement objectives have been emphasized, as demonstrated by the report on program spending in the *National Anti-Drug Strategy Evaluation*. The modernization of the *CDSA* legislative framework offers a significant opportunity to contribute to the greater advancement of public health and patient safety goals by establishing mechanisms that support prevention, treatment and harm reduction. This approach supports the Government of Canada's Throne Speech commitment to address prescription drug abuse as part of the National Anti-Drug Strategy.

In 2013, the CMA's General Council, often referred to the *Parliament of Canadian Medicine*, recommended "that there be an increased emphasis on public health-oriented approaches by regulatory authorities responsible for psychoactive substances." Substance abuse is a complex behaviour influenced by many factors, and a therefore a public health approach to addressing it should incorporate a comprehensive multi-factorial strategy.

A public health approach would place an increased focus on preventing drug abuse and misuse; on treatment of addiction and other consequences of misuse; on monitoring, surveillance and research; and on harm reduction. It would seek to ensure the harms associated with enforcement (e.g. crime, disease due to use of dirty needles) are not out of proportion to the direct harms caused by substance abuse. The CMA recommends that the modernization of the *CDSA* legislative framework focus on enabling and supporting such a public health approach.

It should be noted that the substances governed by the *CDSA* include medications used by patients and prescribed by health care professionals for legitimate therapeutic purposes. We note that the schedules attached to the *CDSA* do not make a distinction between illicit substances of abuse and prescription medication. For example, Schedule I includes both illicit substances such as heroin, and opioid prescription medicines like oxycodone and hydrocodone. The potential of a drug or medication to cause harm has little if anything to do with its legal status. Therefore, the CMA recommends that as part of the review of the *CDSA* and its regulations, Health Canada undertake a review of the schedules, including the organization of the schedules, and the listing of substances within each schedule. The purpose of this review is to ensure that: (1) the schedules are up-to-date; (2) the *CDSA* allows for the incorporation of new illicit substances and prescription medication on the basis of available evidence and in a timely manner; and, (3) the schedules are organized based on risk status, legal status or other consideration.

In the following sections, the CMA outlines recommendations that would facilitate the expansion of a public health approach.

A) Establish Mechanisms to Address Prescription Drug Misuse and Abuse

The misuse and abuse of controlled psychoactive prescription medicines, notably opioids such as oxycodone, fentanyl and hydrocodone, is a significant public health and patient safety issue. Canada has the second highest per capita consumption of prescription opioids in the world, after the United States.

The abuse and misuse of prescription opioids among vulnerable populations, remains a significant concern. For instance, in 2013 opioids were reported as the third most common drug (after alcohol and marijuana) used by students in Ontario. While accurate data on the prevalence of the misuse of prescription medication among seniors is lacking, the CMA is concerned that as Canada's population ages, an increasing number of seniors will need treatment for harms related to prescription medication use, such as drug interactions, falls due to drowsiness or lack of coordination.

Controlled prescription medications are legal products intended for legitimate therapeutic purposes, i.e. to control pain from cancer or terminal illness, or from chronic conditions such as nerve damage due to injury. However, they may also be misused or abused, and addiction may drive some users to illegal behaviour such as doctor-shopping, forging prescribers' signatures, or buying from street dealers.

Canada's physicians are deeply concerned about the misuse and abuse of prescription opioid medication for a number of reasons. First, physicians need to assess the condition of the patient who requests the medication, and consider whether its use is clinically indicated and if the benefits outweigh the risks. Secondly, they may need to prescribe treatment for

patients who have become addicted to the medication. Finally, they are vulnerable to patients who forge the physician's signature or use other illegal means to obtain prescriptions, or who present with fraudulent symptoms, or plead or threaten when denied the drugs they have requested.

The 2014 federal budget promises \$44.9 million over 5 years to the National Anti-Drug Strategy to address prescription drug abuse, and CMA believes that this is a positive step. Health Canada, in its role as drug regulator, could use the *Controlled Drugs and Substances Act* to help further this strategy in the following ways:

i) Improving the approval, labelling and safety monitoring of controlled substances

The CMA recommends that new sections be introduced to the *CDSA* to require higher levels of regulatory scrutiny for controlled prescription medication, during both the approval process and post-approval surveillance. Specifically, the *CDSA* should be amended to require:

- *More stringent pre-approval requirements for controlled prescription medication.* Because of their high level of risk, Health Canada could require that they be subject to higher levels of scrutiny than other medications during the review of pre-approval clinical trial results, special post-approval conditions (e.g. formal post-market studies);
- *Stricter conditions on the marketing* of controlled medication by the pharmaceutical industry to health professionals.
- *Tamper-resistant formulations* of prescription opioid medication. New opioid medication or potentially addictive formulations should be tamper-resistant to reduce the potential for misuse or abuse.
- *Improved patient information* and counseling to be offered to prescribers, dispensers, and patients receiving opioid prescriptions.

ii) Establishing consistent requirements for prescription monitoring

In our brief to the House of Commons Standing Committee on Health (see Appendix A), during its study on prescription drug abuse, the CMA encouraged all levels of government to work with one another and health professional regulatory agencies to develop a pan-Canadian system of real-time prescription monitoring and surveillance. Indeed, all stakeholders who testified before the Committee recognized the importance of prescription monitoring programs in addressing prescription drug abuse.

While prescription monitoring programs (PMPs) exist in most provinces, they vary considerably in terms of quality, the nature of the information they require, whether health care practitioners have real-time access, and in the purpose for which the data is collected. Standardization of surveillance and monitoring systems can contribute to addressing the misuse and abuse of prescription medication by:

- Allowing health care practitioners to identify fraudulent attempts to obtain a prescription, such as an attempt to fill prescriptions from a number of different providers, at the time the prescription is requested or filled.
- Deter interprovincial or jurisdictional fraud, again, by allowing health care practitioners to identify fraudulent attempts at the time the prescription is requested or filled.
- Improve professional regulatory bodies' capacity for oversight and intervention, by establishing a mechanism for real-time monitoring.
- Finally, help Canada's researchers improve our knowledge of this serious public health concern, identify research priorities, and determine best practices to address crucial issues.

Such a system should be compatible with existing electronic medical and pharmacy record systems and with provincial pharmaceutical databases such as that of British Columbia. Participation in prescription monitoring programs should not impose an onerous administrative burden on health care providers. Integration with electronic health records and the widespread use of electronic databases and transmission would go far to minimize the potential burden.

The CMA recommends that a new reporting regulation be promulgated under the CDSA that addresses reporting requirements and disclosure requirements of practitioners, manufacturers and other stakeholders, in order to establish consistent standards for prescription monitoring. This regulation should:

- Enable inter-jurisdictional accessibility and operability;
- Ensure that practitioners have real-time access to the monitoring system;
- Enable electronically-based prescription monitoring; and;
- Conform to privacy laws, protecting patient confidentiality while enabling the sharing of necessary information. (Privacy concerns are addressed in greater detail in Part 2).

B) Supporting harm reduction as a component of a drug strategy

The CMA fully endorses harm reduction strategies and tools, including supervised injection sites, and believes that the CDSA should support and enable them. It is the CMA's position that addiction should be recognized and treated as a serious medical condition.

Section 56 of the CDSA sets out conditions under which applicants may obtain exemptions from the provisions of the Act. Bill C-2, currently at Second Reading in the House of Commons, proposes new, far reaching, and stringent conditions that must be met by a proponent who is applying to establish a supervised injection site. The CMA maintains that safe injection sites are a legitimate form of treatment for the disease of addiction, that their

benefit is supported by a body of research, and that the conditions proposed under Bill C-2 are overly restrictive.

In addition, to support harm reduction, the CMA encourages Health Canada to amend section 2 (2) (b) (ii) (B) of the CDSA that states a controlled substance includes “any thing that contains or has on it a controlled substance and that is used or intended or designed for use... in introducing the substance into a human body” in order to enable the important role of safe injection sites.

C) Developing clinical knowledge base about the medical use of marijuana

The CMA has already made its position on the *Marihuana for Medical Purposes Regulations* known to Health Canada (see Appendix B). Despite repeated revisions since they were first established in 2001, the regulations do not address CMA’s primary concern; that physicians are made gatekeepers for a product whose medical benefits have not been sufficiently researched, and which has not undergone the clinical trial process required for therapeutic products under the *Food and Drugs Act*. The absence of clinical evidence means that physicians lack scientific information and guidance on the uses, benefits and risks of marijuana when used for medicinal purposes. To address these issues, the CMA recommends that Health Canada invest in scientific research on the medical uses of marijuana. This could include establishing market incentives for Licensed Producers to undertake research, or requiring them to contribute to a research fund administered by the Canadian Institutes of Health Research. In addition, the CMA encourages the development and dissemination of evidence-based clinical support tools for physicians.

Part 2: Ensuring protection of patient privacy

In any legislative framework pertaining to patient care, physicians consider protecting the privacy of patient information to be paramount; indeed, privacy, confidentiality and trust are cornerstones of the patient-physician relationship (see Appendix C). For these reasons, the CMA strongly recommends that Health Canada undertake a privacy impact assessment of the existing CDSA and its regulations as well as of future proposed amendments. The CMA encourages Health Canada to make this assessment available to stakeholders as part of its consultation process on this legislative framework.

As previously mentioned, the new regulation proposed under Part 1 (A) (ii) above must conform to privacy laws, and protect patient confidentiality while enabling the sharing of necessary information.

The CMA is deeply concerned with the search provision under s.31 of the CDSA in which an exception to this broad authority for patient records is mentioned in subsection (1) (c). The CMA is concerned that this exception may not be sufficient to meet the existing privacy laws governing patient information and records, both federally and provincially. As such, the CMA

recommends that the CDSA be amended to ensure that patient information and records are exempt from search authorities, consistent with the most stringent privacy laws at the federal and provincial jurisdictions.

Part 3: Enabling e-prescribing

As part of the review of the CDSA and its associated regulations, Health Canada should assess how this legislative framework may be used to facilitate and support the advancement of e-health, specifically e-prescribing. Electronic health records can support individual physicians or pharmacists to quickly identify potential diversion and double-doctoring, at the point where a prescription is written or filled. The electronic health record also facilitates the sharing of information among health professionals, as well as programs that allow physicians to compare their prescribing practices to those of their peers.

For instance, sections of the *Benzodiazepines and Other Targeted Substances Regulations*, *Narcotic Control Regulations*, and *Precursor Control Regulations*, establish the conditions within which pharmacists may accept a prescription. The CMA recommends that these regulations be amended to specifically include electronic prescriptions in addition to verbal and written prescriptions among the forms that may be accepted by a pharmacist. This recommendation is consistent with the joint statement by the CMA and the Canadian Pharmacists Association on e-prescribing (see Appendix D).

Health Canada should also ensure that regulatory amendments facilitate prescription monitoring, as discussed in a previous section.

Part 4: Establishing a mechanism for changes to scope of practice

The *New Classes of Prescribers Regulations*, promulgated in 2012, grants nurse practitioners, midwives and podiatrists the authority to prescribe controlled substances if their provincial scope of practice laws permit. The CMA's 2012 submission in response to this regulatory change is attached to this brief for information (Appendix E.) In it, the CMA recommended that "A regulatory framework governing prescribing authority, or any other aspect of scope of practice, should always put patient safety first. The primary purpose of scope of practice determination is to meet the health care needs and serve the health interests of patients and the public safely, efficiently, and competently." One of our main concerns at the time was that the more practitioners who could prescribe controlled substances, the greater the potential for the illegal diversion of products to street dealers. This remains a concern for us.

Given the significance of scope-of-practice determinations to patient safety and patient care, the CMA strongly recommends that future changes to the scope of practice of a health care practitioner be undertaken only within a defined, transparent evaluation process based on clinical criteria and protection of patient safety.

To this end, the CMA strongly recommends the introduction of new clauses to the CDSA and its associated regulations to establish a mechanism that governs future changes to scope of practice. These clauses should require, prior to the implementation of any change:

- Demonstration that it will improve public health and patient safety;
- Meaningful consultation with professional organizations and regulatory authorities; and,
- Support of provincial and territorial ministers of health.

Further, the CMA recommends that such a new regulation governing possible future changes to scope of practice require:

- That new classes of prescribers have conflict of interest policies;
- That new classes of prescribers be incorporated under the prescription monitoring regulation recommended under Part 1 (A) (ii) above; and
- That a mandatory five-year review be established for new classes of prescribers.

Part 5: Recognizing the authority of physician regulatory colleges

As previously mentioned, many controlled substances governed under the CDSA and its associated regulations are prescribed by physicians and other health professionals, for therapeutic purposes.

Medicine is a regulated profession, and the colleges of physicians have ultimate authority and responsibility for the oversight of physician practice, including monitoring prescribing activity, investigating practice and when required, taking disciplinary action.

In its present form, section 59 of the *Narcotic Control Regulations* includes a duplicative and redundant provision for oversight and disciplinary action. The CMA strongly recommends that this section be amended to recognize the established authority of physician regulatory colleges for the oversight of the medical profession.

Conclusion

The CMA welcomes the consultation and review of the *Controlled Drugs and Substances Act* and its associated regulations. As mentioned before, this submission is not an exhaustive analysis of the *Controlled Drugs and Substances Act*, but an initial summary of CMA's position on issues of particular concern to patient safety and public health. This brief outlines numerous opportunities within the CDSA and its associated regulations to establish new measures and mechanisms that would contribute to improved public health and patient safety.

In light of the breadth and importance of the issues raised in this review, CMA encourages further consultation and welcomes the opportunity to discuss these issues in greater detail.

List of Appendices:

- Appendix A: CMA Brief to the House of Commons Standing Committee on Health – [The Need for a National Strategy to Address Abuse and Misuse of Prescription Drugs in Canada](#)
- Appendix B: CMA Policy Statement – [Medical Marijuana](#)
- Appendix C: CMA Policy Statement – [Principles for the Protection of Patient’s Personal Health Information](#)
- Appendix D: CMA Policy Statement – [Vision for e-Prescribing: a joint statement by the Canadian Medical Association and the Canadian Pharmacists Association](#)
- Appendix E: CMA submission – Response to the proposed New Classes of Practitioners regulations published in the Canada Gazette Part I (Vol. 146, No. 18 – May 5, 2012)

Overview of recommendations

The CMA recommends that the modernization of the *CDSA* legislative and regulatory framework should be guided first and foremost by the objective of improving public health, promoting quality care and enhancing patient safety.

The CMA recommends that as part of the review of the *CDSA* and its regulations, Health Canada undertake a review of the schedules, including the organization of the schedules, and the listing of substances within each schedule.

The CMA recommends that new sections be introduced to the *CDSA* to require higher levels of regulatory scrutiny as part of the approval and post-approval process for prescription opioid medication.

The CMA recommends that a new reporting regulation be promulgated under the *CDSA* that addresses reporting requirements and disclosure requirements of practitioners, manufacturers and other stakeholders in order to establish consistent standards for prescription monitoring.

To support harm reduction, the CMA recommends an amendment to section 2 (b) (ii) of the *CDSA*, which states a controlled substance includes “any thing that contains or has on it a controlled substance and that is used or intended or designed for use... in introducing the substance into a human body”.

The CMA recommends that Health Canada invest in scientific research on the medical uses of marijuana. This could include establishing market incentives that require Licensed Producers to undertake research, or requiring them to contribute to a research fund administered by the Canadian Institutes of Health Research. In addition, the CMA encourages the development and dissemination of evidence-based clinical support tools for physicians.

The CMA recommends that Health Canada undertake a privacy impact assessment of the existing *CDSA* and its regulations as well as future proposed amendments, and provide this assessment to stakeholders as part of its consultation process on this legislative framework.

The CMA recommends that the *CDSA*, specifically s.31 (1) (c), be amended to ensure that patient information and records are exempt from search authorities, consistent with the most stringent privacy laws at the federal and provincial jurisdictions.

The CMA recommends that the *CDSA* and its regulations be amended to specifically include electronic prescriptions in addition to verbal and written prescriptions among the forms that may be accepted by a pharmacist, including sections within the *Benzodiazepines and Other Targeted Substances Regulations*, *Narcotic Control Regulations*, and *Precursor Control Regulations*.

The CMA recommends the introduction of new clauses to the CDSA and its associated regulations to establish a mechanism that governs future changes to scope of practice, based on the introduction of a new regulation governing changes to scope of practice that will require, prior to the implementation of any change:

- Demonstration of public health and patient safety improvement;
- Meaningful consultation with professional organizations and regulatory authorities; and,
- Support of provincial and territorial ministers of health.

The CMA recommends that the new mechanism of the CDSA legislative framework governing possible future changes to scope of practice require:

- That new classes of prescribers have conflict of interest policies;
- That new classes of prescribers be incorporated under the prescription monitoring regulation recommended under Part 1 (A) (ii) above; and
- That a mandatory five-year review be established for new classes of prescribers.

The CMA strongly recommends that s.59 of the *Narcotic Control Regulations* be amended to recognize the established authority of physician regulatory colleges for the oversight of the medical profession.