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November 8, 2017

Michelle Boudreau
Director General
Controlled Substances Directorate
Office of Legislative and Regulatory Affairs
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Dear Ms. Boudreau

RE: NON-PRESCRIPTION AVAILABILITY OF LOW-DOSE CODEINE PRODUCTS

On behalf of the Canadian Pharmacists Association (CPhA), we would like to thank you for the opportunity to comment on Health Canada's proposed amendments to the Narcotic Control Regulations under the Controlled Drugs and Substances Act, which would require that all products containing codeine (an opioid) be sold by prescription only.

As the national voice of the profession, CPhA is committed to pharmacy practice excellence and optimal health outcomes for Canadians through safe and effective drug therapy. CPhA is pleased that the federal government is taking steps to make all codeine products available only by prescription, which is in alignment with recommendations CPhA made in a letter to Health Minister Jane Philpott in November 2016. We believe this is an essential piece of legislation that would increase efforts to mitigate opioid addiction as well as protect Canadians from the health risks of low-dose combination opioid products.

Pharmacists across the country are often the first point of contact for patients within our health care system. As drug experts, pharmacists are relied upon by their patients to ensure their safety with regards to drug therapy and provide expert advice related to all medications, including over- and behind-the-counter medicines. For some time, pharmacists have been challenged by the availability of non-prescription low-dose codeine products as they are known to have little benefit over non-codeine containing analgesics but are associated with considerable harms. Moreover, pharmacists, lacking access to the appropriate monitoring tools, have been limited in their ability to effectively restrict patient access to these addictive and potentially harmful drugs. We therefore support Health Canada in its proposal to require all products containing codeine to be sold by prescription only.



Patient safety

Pharmacists understand first-hand the addictive nature of low-dose, codeine-containing pain medications, which have proven to be a product of concern in Canada's opioid crisis and internationally. According to a Star investigation published in 2015, more than 500 people entered methadone treatments from 2012 to 2015 for addictions to low-dose codeine products.¹ An article published in the *Canadian Pharmacists Journal* referenced a number of Canadian studies showing misuse of these products, including the following:²

- A 1997 Canadian survey of regular codeine users, which found that 37% were dependent on codeine, 4% abused it, and one-half of all regular users obtained codeine over the counter.³
- A retrospective chart review of patients attending a methadone maintenance treatment clinic from 1997 to 1999 in Toronto, Ontario, where 46% of opioid users were using codeine and 35% of opioid users were using OTC codeine.⁴
- A chart review of patients attending an opioid detoxification program in Toronto, Ontario, from 2000 to 2004, where 35% reported using codeine and 5% were using low-dose, non-prescription codeine.⁵

Beyond the dangers of misuse and addiction, low-dose codeine products are sold in combination with non-opioid analgesics, such as acetylsalicylic acid (ASA) and acetaminophen. It is widely known that in high doses these analgesics may result in serious adverse effects, which include liver toxicity, gastric perforation, haemorrhage and peptic ulcer, renal failure, chronic blood loss anaemia and low blood potassium (with potential fatal heart and neurological complications). Those addicted to low-dose codeine products are at risk of ingesting dangerous amounts of these analgesics.

Efficacy of low-dose codeine combination analgesics

Taking into consideration the risks associated with high doses of simple analgesics, the addictive potential of codeine, as well as the overall effectiveness of analgesics containing codeine compared to non-opioid analgesics, there is limited evidence available that would support the use of low-dose codeine pain medication over non-opioid analgesics.⁶ The Canadian Medical Association has even suggested that the potential risks associated with codeine warrant its phasing out altogether as an analgesic option.⁷ Given the state of the opioid crisis in Canada, it is imperative that we find appropriate alternatives to opioids, where possible. Therefore, along with our recommendation to regulate low-dose codeine products, we would encourage Health Canada to undertake a critical review of the clinical evidence in support of low-dose, as well as all, codeine products.

Challenges with the current system

Pharmacists are on the front lines of the opioid crisis and are relied upon to provide expert medication counseling, monitoring, addiction management therapy, and participate in harm reduction strategies. As



patient safety is a top priority for pharmacists at all times, we believe additional safeguards would support better utilization and address existing challenges within the system.

Gaps in the current system that allow for the misuse of low-dose codeine products include limited access by pharmacists to patient medical histories through electronic health records (EHR), medication histories through drug information systems (DIS) and prescription monitoring programs (PMP), which are specifically designed to detect drug misuse and diversion. Without these key monitoring tools, pharmacists are unable to know if a request for low-dose codeine is appropriate for the patient. Patients who misuse codeine may also be quite savvy to the system's monitoring flaws; convince pharmacists that no other analgesics have worked to manage their pain; and be persistent by visiting multiple pharmacies until they are able to obtain the product.

By continuing to authorize the availability of codeine as a non-prescription product at the same time as we move further towards encouraging patient self-care, policy-makers are contributing to the idea that low-dose codeine products are safe and effective treatment options. In fact, there are reports that misuse and harm from combination codeine products may be growing in countries where they are available without a prescription.⁸ Without considerable investments in integrated EHR, DIS and PMP tools, pharmacists will continue to be significantly challenged to prevent the growing misuse and dangers associated with non-prescription codeine.

The Role of Pharmacists

In full support of the move to regulate low-dose codeine products, CPhA acknowledges the importance of helping patients manage the impact of this change, particularly patients who are experiencing addiction. Once low-dose codeine products are no longer available without a prescription, community pharmacists will be responsible for communicating this change to patients and helping patients manage symptoms of withdrawal.

If we are going to effectively combat the opioid crisis in Canada we need to fully leverage the knowledge, skills and expertise of pharmacists. Regulatory changes have been introduced in most provinces to authorize pharmacists to prescribe and adapt prescriptions. This can involve making adjustments to dosing, quantities, dosage forms and/or dosage regimens for a particular medication. However, the *Controlled Drugs and Substances Act* (CDSA) currently does not include pharmacists in the list of practitioners who can prescribe CDSA-scheduled drugs. This prevents pharmacists from using their prescribing authority to adapt prescriptions for opioids.

CPhA believes that designating pharmacists as practitioners under the CDSA is a meaningful and effective action to help combat the opioid crisis in Canada. It is common for community pharmacists to receive prescriptions for inappropriate dosages and quantities of initial opioid prescriptions. By amending the CDSA to include pharmacists, they would have the ability to reduce the dosage and/or quantity of opioids where appropriate and instead consider prescribing alternative therapies. With EHR and DIS enablers, pharmacists would have a significant impact on appropriate medication management and patient outcomes.



Conclusion

CPhA commends Health Canada for its comprehensive strategy in addressing the opioid crisis. With drug overdoses quickly becoming one of the leading causes of death in Canada, there is no question that Canada should join other leading countries and add the regulation of low-dose codeine to the list of tactics being implemented to prevent misuse and addiction to opioids.

CPhA is firmly committed to providing national leadership on this issue and working collaboratively with Health Canada and partners to eliminate the availability of low-dose codeine as a non-prescription product. We would also welcome opportunities to engage further with Health Canada to demonstrate how opioid therapy can be better managed and patient safety improved by designating pharmacists as practitioners under the CDSA.

We thank Health Canada for the opportunity to provide comments on mechanisms and processes that aim to create a safer health system for Canadians, particularly as they relate to opioid and pain management. Should you have any questions related to this submission, please contact me at 613-523-7877 or by email at ikrawchenko@pharmacists.ca.

Yours sincerely,

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¹ Star investigation: Canada's invisible codeine problem. Yan J, Zlomislic D. Jan 2015. Available:

<https://www.thestar.com/news/canada/2015/01/17/star-investigation-canadas-invisible-codeine-problem.html>

² MacKinnon J. Tighter regulations needed for over-the-counter codeine in Canada. *Can Pharm J* 2016;6:322-324. Available: <http://journals.sagepub.com/doi/full/10.1177/1715163516660572>

³ Sproule B, Busto U, Somer G. Characteristics of dependent and nondependent regular users of codeine. *J Clin Psychopharmacol* 1999;19:367-72

⁴ Brands B, Blake J, Sproule B. Prescription opioid abuse in patients presenting for methadone maintenance treatment. *Drug Alcohol Depend* 2004;73:199-207.

⁵ Sproule B, Brands B, Li S. Changing patterns in opioid addiction. *Can Fam Physician* 2009;55:68-69.e5

⁶ MacKinnon J. Tighter regulations needed for over-the-counter codeine in Canada. *Can Pharm J* 2016;6:322-324. Available: <http://journals.sagepub.com/doi/full/10.1177/1715163516660572>

⁷ MacDonald N, MacLeod S. Has the time come to phase out codeine? *Can Med Assoc J* 2010;182:1825. Available: <http://www.cmaj.ca/content/182/17/1825.full>

⁸ McAvooy B, Dobbin M, Tobin C. Over-the-counter codeine analgesic misuse and harm: characteristics of cases in Australia and New Zealand. *N. Z. Med. J.* 2011;124:1346. Available: <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2011/vol-124-no-1346/article-mcavoy>