

CMA Submission: Non-Prescription Availability of Low-Dose Codeine Products

Submission to the Health Canada consultation on the potential risks, benefits and impacts of changes to the regulations to the *Controlled Drugs and Substances Act* that would require all products containing codeine to be sold by prescription only

November 7, 2017

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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is empowering and caring for patients, with a vision for a vibrant profession and a healthy population.

On behalf of its more than 85,000 members and the Canadian public, the CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and over 60 national medical organizations.

The Canadian Medical Association (CMA) is pleased to provide this submission in response to Health Canada's notice as published in the *Canada Gazette*, Part I¹ for interested stakeholders to provide comments on the potential risks, benefits, and impacts of changes to the regulations to the *Controlled Drugs and Substances Act* that would require all products containing codeine to be sold by prescription only.

Codeine is a widely used narcotic analgesic in Canada – low dose formulations are currently sold without a prescription, when in combination with at least two other medications. It is not available for self-selection, but kept behind the counter in pharmacies.

However, serious concerns have been raised about the safety of this practice in recent years.^{2,3,4} A literature review examining over the counter medicine abuse in several countries found that “there is a recognized problem internationally involving a range of medicines and potential harms,” including codeine-based medicines.⁵

Doctors support patients in the management of acute and chronic pain, as well as addictions, and as such we have long been concerned about the harms associated with opioid use, including codeine. Codeine is considered to be “a poor analgesic in its own right,” for which there are more suitable alternatives.⁶ In addition, genetic factors can substantially affect the metabolism of codeine into morphine, resulting in concentrations that vary from person to person. This can lead to potentially serious consequences, even at conventional doses, particularly in children.²

Codeine has the potential for dependence. Studies show an increase in non-therapeutic use of codeine, including over the counter formulations, leading to increases in morbidity and mortality as well as social costs.^{7,8,9} An Australian study noted that “codeine-related deaths (with and without other drug toxicity) are increasing as the consumption of codeine-based products increases.”¹⁰ Ontario data shows that over 500 people began methadone treatment for non-prescription codeine, between 2011 and 2014.³

In addition, over the counter codeine is often combined with acetaminophen or ASA, which also present concerns in terms of toxicity, particularly in higher doses.

A review of the process examining the problems related to codeine-based over the counter formulations in Australia, New Zealand, and the United Kingdom found that each of their respective committees had decided, based on the existing evidence, “to minimize harm by using regulatory levers to restrict availability.”¹¹ Many European countries have also implemented a prescription-only status for products containing

codeine, as well as some U.S. States. Some Canadian hospitals have removed codeine from their formularies, and Manitoba ended the over the counter sales last year¹².

Given this reality and, as part of the CMA's advocacy to reduce the harms related to opioid use, the CMA supports the requirement that all products containing codeine be sold by prescription only, as this is both a public health and a patient safety issue.

Moving codeine to prescription-only will enable limiting its use and closer monitoring of patients with the view of preventing harms.¹⁰ A challenge for policy makers and prescribers is to ensure patients still have access to treatments that are appropriate for their clinical conditions.¹³

At the same time, we recognize that there could be unintended consequences when moving low-dose codeine to prescription-only status, particularly for those who have come to depend on its availability over-the-counter. Some may choose to seek out illicit markets for these products or purchase other, more powerful, narcotics as a substitute. Authorities must develop educational tools to inform people about less-harmful pain-relief options. As well, a reasonable timeframe for implementation of this measure should be given to allow for patients to find appropriate alternatives.

The CMA continues to urge governments to increase access to services and treatment options for addiction and pain management, as well as harm reduction.¹⁴

¹ Controlled Drugs and Substances Act: Notice to interested parties - Non-prescription availability of low-dose codeine products. *Canada Gazette Part I*. 2017 Sep 09, 151(36). Available: <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-09-09/html/notice-avis-eng.php#ne3> (accessed 2017 Nov 07).

² MacDonald N, MacLeod SM. Has the time come to phase out codeine? *Can Med Assoc J* 2010;182(17):1825. Available: <https://doi.org/10.1503/cmaj.101411> (accessed 2017 Nov 07).

³ Yang J, Zlomislic D. Star investigation: Canada's invisible codeine problem. *The Toronto Star*. Jan. 17, 2015. Available: <https://www.thestar.com/news/canada/2015/01/17/star-investigation-canadas-invisible-codeine-problem.html> (accessed: 2017 Nov 7).

⁴ MacKinnon, JIJ. Tighter regulations needed for over-the-counter codeine in Canada. *Can Pharm J Rev Pharm Can*, 2016;149(6):322-4. Available: <http://www.cmaj.ca/content/182/17/1825> (accessed 2017 Nov 07).

⁵ Cooper RJ. Over-the-counter medicine abuse – a review of the literature. *J Subst Use*, 2013 Apr;18(2):82-107. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603170/pdf/JSU-18-82.pdf> (accessed: 2017 Oct 23).

⁶ Vagg M. Four reasons why codeine should not be sold without a prescription. *The Conversation*. Apr. 30, 2015. Available: <http://theconversation.com/four-reasons-why-codeine-should-not-be-sold-without-prescription-41025> (accessed: 2017 Oct 23).

⁷ Nielsen S, Cameron J, Pahoki S. *Over the counter codeine dependence final report 2010*. Victoria: Turning Point, 2010. Available: http://atdc.org.au/wp-content/uploads/2011/02/OTC_CODEINE_REPORT.pdf (accessed 2017 Nov 07).

⁸ Fischer B, Ialomiteanu A, Boak A, *et al.* Prevalence and key covariates of non-medical prescription opioid use among the general secondary student and adult populations in Ontario, Canada. *Drug Alcohol Rev* 2013;32(3):276–87.

⁹ Compton WM, Volkow ND. Major increases in opioid analgesic abuse in the United States: concerns and strategies. *Drug Alcohol Depend* 2006 Feb 01;81(2):103–7.

¹⁰ Roxburgh A. *et al.* Trends and characteristics of accidental and intentional codeine overdose deaths in Australia. *Med J Aust* 2015; 203(7): 299

¹¹ Tobin CL, Dobbin M, McAvoy B. Regulatory responses to over-the-counter codeine analgesic misuse in Australia, New Zealand and the United Kingdom. *N Z J Public Health* 2013 Oct. 37(5): 483-488. Available: <http://onlinelibrary.wiley.com/doi/10.1111/1753-6405.12099/abstract> (accessed: 2017 Nov 7).

¹² Zlomislic, D. & Yang, J. *The Toronto Star*. Jan 12, 2016. Available: https://www.thestar.com/life/health_wellness/2016/01/13/manitoba-sets-new-rule-limiting-codeine.html (accessed: 2017 Nov 7).

¹³ Canadian Medical Association. *Opening Statement addressing the opioid crisis to the House of Commons Standing Committee on Health*. Ottawa: The Association; 2016 Oct. Available: <https://www.cma.ca/Assets/assets-library/document/en/advocacy/submissions/hesa-opioid-study-opening-remarks-oct-18-2016-e.pdf> (accessed: 2017 Nov 7).

¹⁴ Canadian Medical Association. *Harms Associated with Opioids and Other Psychoactive Prescription Drugs*. CMA Policy, 2015. Ottawa: The Association; 2015. Available: https://www.cma.ca/Assets/assets-library/document/en/policies/cma_policy_harms_associated_with_opioids_and_other_psychoactive_prescription_drugs_pd15-06-e.pdf (accessed: 2017 Nov 7).