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August 14, 2018

Michelle Boudreau
Director General
Office of Legislative and Regulatory Affairs
Controlled Substances Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
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By email: hc.csd.regulatory.policy-politique.reglementaire.dsc.sc@canada.ca

Dear Ms. Boudreau

RE: Proposal to add tramadol to Schedule I of the *Controlled Drugs and Substances Act* and the Schedule to the *Narcotic Control Regulations*

On behalf of the Canadian Pharmacists Association (CPhA), we would like to thank you for the opportunity to comment on Health Canada's proposal to amend Schedule I to the *Controlled Drugs and Substances Act* (CDSA) and the Schedule to the *Narcotic Control Regulations* (NCR) to include tramadol, its salts, isomers and derivatives and the salts and isomers of its derivatives.

CPhA is the national voice of Canada's 41,000 pharmacists. Every day, pharmacists provide counseling to patients on the appropriate use of prescription opioids at the time of dispensing. They further monitor long-term opioid use through medication review services; support addiction management therapy for Canadians; and participate in harm reduction strategies, such as dispensing and training patients on the overdose-reversing drug naloxone.

CPhA is pleased with the government's decision to reschedule tramadol as a controlled narcotic. This decision aligns with recommendations made by CPhA in a [position statement](#) issued in May 2018. Further to the reclassification of tramadol, CPhA also recommends a critical review of the clinical evidence in support of combination opioid analgesics as well as changes to the CDSA that would allow pharmacists to play a greater role in the management of their patients' opioid therapies.



Reclassification of tramadol as a Schedule 1 narcotic under the Controlled Drugs and Substances Act

Tramadol is a prescription-only opioid medication used as an analgesic for the treatment of pain and marketed in Canada since 2005. It increases serotonin levels and converts within the liver to an opioid that relieves pain. The analgesic effect of tramadol is unpredictable and dependent on a specific enzyme, which varies from person to person as well as between ethnic groups. Like other opioids, tramadol poses risks of opioid addiction, abuse, and misuse, which can lead to overdose and death.^{1,2}

As tramadol is not currently subject to the same reporting requirements as narcotics listed in the CDSA, there is a lack of information available about the extent of its abuse and misuse.³ However, in November 2017, the Canadian Institute for Health Information released a report on the amount of opioids prescribed in Canada. The report revealed that while, overall, the amount of opioids being prescribed is dropping, tramadol prescriptions had increased by 30 percent from 2012 to 2016, and tramadol is among six opioids that account for more than 96 percent of all opioid prescriptions in Canada.⁴

Despite the classification of tramadol as an opioid analgesic and its inclusion in the *2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain*, the drug has never been scheduled under the Controlled Drugs and Substances Act (CDSA). This has misrepresented the potential dangers associated with tramadol and made it easier to prescribe than other opioids, given there are no reporting requirements for non-CDSA scheduled drugs. A reclassification of tramadol as a Schedule 1 narcotic would list this drug alongside other opioids, such as morphine and codeine. This would ensure that the prescribing, dispensing and storage of tramadol are subject to stricter controls, including enhanced reporting, to prevent its potential abuse and diversion.⁵ This reclassification would also eliminate the perception among health care providers and patients that tramadol may be a safer analgesic alternative than other opioids.

CPhA strongly supports the reclassification of tramadol as a Schedule 1 narcotic under the Controlled Drugs and Substances Act. Given the current national opioid crisis in Canada, where 3,987 apparent opioid-related deaths were recorded in 2017, it is essential that tramadol be classified appropriately as an opioid in the CDSA.⁶ We must, furthermore, ensure that patient positions are heard on this issue and that access to appropriate pain management therapy is not compromised. Should tramadol be rescheduled as a Schedule 1 narcotic under the Controlled Drugs and Substances Act, it will be critical for pharmacists and other health care practitioners to communicate this change and help patients manage its impact, particularly patients who are experiencing addiction.

Combination opioid analgesics

Beyond the recommendation to reclassify tramadol, CPhA holds ongoing concerns regarding opioid-containing analgesics, such as Tramacet, which contains both tramadol and acetaminophen. Pharmacists understand first-hand the addictive nature of opioid-containing pain medications and the potential for abuse is especially



dangerous with combination products such as Tramacet. It is widely known that, in high doses, acetaminophen may result in serious adverse effects, including liver toxicity, gastric perforation, haemorrhage and peptic ulcer, renal failure, and low blood potassium (with potential fatal heart and neurological complications). Those addicted to opioid combination products are at risk of ingesting dangerous amounts of these analgesics. **Therefore, CPhA further recommends that Health Canada undertake a critical review of the clinical evidence in support of combination opioid analgesics and consider removing these products from the market to reduce the risk of accidental acetaminophen overdose.**

The role of pharmacists

As medication experts and the most accessible health care practitioners, pharmacists have a critical role to play in controlling inappropriate opioid prescribing and dispensing practices. Regulatory changes have been introduced in most provinces to authorize pharmacists to prescribe or adapt prescriptions in order to address safety or adherence issues or other unique needs of the patient. This can involve making adjustments to dosing, quantities, dosage forms or directions for a particular medication. However, the Controlled Drugs and Substances Act (CDSA) does not currently include pharmacists in the list of practitioners who can prescribe and adapt CDSA-scheduled drugs, such as opioids. This is a missed opportunity to help mitigate the opioid crisis.

It is common for community pharmacists to receive prescriptions for inappropriate dosages and quantities of initial opioid prescriptions. Pharmacists also encounter patients who may require a change or a refill for their opioid or opioid antagonist prescription at times when their physician is unavailable or their clinic is closed. A treatment interruption in this situation may be dangerous if it leads patients to seek opioids from the illegal market. If pharmacists were granted the authority to adapt CDSA-scheduled drugs, they could, where appropriate, help manage patients' opioid therapy by renewing a prescription, reducing the dosage of opioids, administering a patient's opioid tapering plan and recommending and prescribing alternative therapies to opioids, such as non-steroidal anti-inflammatories.

CPhA recommends that changes be made to the CDSA to include pharmacists in the definition of “practitioner.”

These changes are required as a first step to enable provincial governments to make the necessary regulatory changes to authorize this scope of practice change for pharmacists. With the appropriate safeguards and limitations in place, and supported with robust training and certification, these measures would enhance the oversight of opioid therapy management in Canada and improve patient outcomes.

Conclusion

CPhA commends Health Canada for its leadership in addressing the opioid crisis in Canada. The appropriate scheduling of tramadol is just one piece of the larger opioid mitigation strategy, but a critical step that will help prescribers and patients better appreciate the risks associated with this medication and ensure that tramadol prescribing is accompanied by the proper reporting and controls.



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As a next step, CPhA is calling for the review of clinical evidence associated with combination opioid analgesics to determine if the risks they pose to patients outweigh their benefits. We would further implore the government to leverage the skills and expertise of the pharmacist profession and empower pharmacists to adapt opioid prescriptions for the benefit and safety of patients.

CPhA looks forward to our continued work with Health Canada and other key stakeholders to achieve meaningful and effective action to combat the opioid crisis in Canada. Should you have any questions related to this submission, please contact me at 613-523-7877 or by email at pemberley@pharmacists.ca.

Yours sincerely,

Phil Emberley, PharmD, MBA
Director, Practice Advancement and Research

¹ Canadian Pharmacists Association. *Opioids product monographs*. RxTx; Oct 2017. Available: <https://www.e-therapeutics.ca> (accessed: 2018 Jan 23)

² Juurlink, David. "Why Health Canada must reclassify tramadol as an opioid." *The Globe and Mail*. Toronto. 27 Nov 2017. Available: <https://www.theglobeandmail.com/opinion/why-health-canada-must-reclassify-tramadol-as-an-opioid/article37089174/> (accessed: 2018 Jan 23)

³ Howlett, Karen; Baum, Kathryn B. "Health Canada eyes opioid restrictions for popular painkiller." *The Globe and Mail*. Toronto. 22 Nov 2017. Available: <https://www.theglobeandmail.com/news/national/health-canada-eyes-opioid-restrictions-for-popular-painkillertramadol/article37048483/> (accessed: 2018 Jan 23)

⁴ Canadian Institute for Health Information. *Amount of opioids prescribed dropping in Canada; prescriptions on the rise*. 2017. Available: <https://www.cihi.ca/en/amount-of-opioids-prescribed-dropping-in-canada-prescriptions-on-the-rise> (accessed: 2018 Jan 23)

⁵ National Pain Centre. *The 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain*. 2017. Available: http://nationalpaincentre.mcmaster.ca/documents/Opioid%20GL%20for%20CMAJ_01may2017.pdf (accessed: 2018 Jan 23)

⁶ Health Canada. *Apparent opioid-related deaths*. 19 Jun 2018. Available: <https://www.canada.ca/en/health-canada/services/substance-abuse/prescription-drug-abuse/opioids/apparent-opioid-related-deaths.html> (accessed: 2018 Jul 26)