CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA

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Office of Legislative and Regulatory Affairs
Controlled Substances and Cannabis Branch
Health Canada
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By email to: hc.csd.regulatory.policy-politique.reglementaire.dsc.sc@canada.ca

RE: *Canada Gazette, Part I, Volume 153, Number 16: Order Amending Schedule I to the Controlled Drugs and Substances Act (Tramadol)*

On behalf of the Canadian Pharmacists Association (CPhA), we are pleased that Health Canada intends to amend the regulations to include tramadol, M1 and M5, as well as the salts, isomers, and salts of isomers of tramadol, M1 and M5, to Schedule I to the Controlled Drugs and Substances Act (CDSA) and to the Schedule to the Narcotic Control Regulations (NCR).

CPhA is the national voice of Canada's 42,000 pharmacists, who have a critical role to play in the safe and appropriate use of prescription opioids. Community pharmacists counsel patients on the risks and benefits of opioids at the time of dispensing and participate in opioid monitoring programs to help detect potential harms and misuse of prescribed opioid therapy. Pharmacists also help patients manage and treat opioid dependency with pharmacological treatment options, such as methadone and buprenorphine/naloxone, and across Canada pharmacists are contributing to opioid harm reduction strategies through the distribution of naloxone and associated education.

CPhA has long held concerns about tramadol remaining unscheduled under the CDSA. We have expressed these concerns in our position statement issued in May 2018 and within the tramadol consultation of August 2018. Like other opioids, tramadol poses risks of opioid addiction and misuse, which can lead to overdose and death. Even though it is considered a weak opioid, its analgesic effect is unpredictable and dependent on a specific enzyme, which varies from person to person as well as between ethnic groups. According to the Canadian Institute for Health Information, while the amount of opioids being prescribed in Canada is dropping overall, tramadol prescriptions 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.[1]

A reclassification of tramadol as a Schedule I narcotic would list this drug alongside other opioids, such as morphine and codeine, and ensure that the prescribing, dispensing and storage of tramadol are subject to stricter controls. For example, prescribers would no longer be able to order refills of tramadol without first assessing and consulting with their patients. Health care providers would also be required to adhere to strict reporting and storage requirements to prevent potential diversion and abuse. Further, the reclassification of tramadol would

eliminate a possible perception among health care providers and patients that it may be a safer analgesic alternative than other opioids because of its unscheduled status.

Given the toll that this crisis has taken on the health and life expectancy of Canadians, the federal government has a responsibility to do everything within its scope and mandate to mitigate this crisis, including the appropriate scheduling of opioids within the Canadian market. And while a reclassification of tramadol may lead to incurred costs by the pharmaceutical industry, government, patients and pharmacies, we believe these costs are well worth the benefits from the stricter control of this potentially harmful opioid medication.

Combination opioid analgesics

Beyond the reclassification of tramadol as a Schedule I narcotic, CPhA is also calling for a review of all 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 that contain acetaminophen. 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 for fatal heart and neurological complications). Those addicted to opioid combination products are at risk of ingesting dangerous amounts of these analgesics. Therefore, CPhA 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, pharmacists are eager to do more to help address inappropriate opioid prescribing and dispensing practices. Regulatory changes have been introduced in most provinces that authorize pharmacists to prescribe or adapt prescriptions to suit the individual needs of their patients. This can involve making adjustments to dosing, quantities, dosage forms or directions for a particular medication. However, the CDSA does not currently include pharmacists in the list of practitioners who can prescribe and adapt CDSA-scheduled drugs. This is a missed opportunity to allow the most accessible health care practitioners to take on an expanded role in mitigating and addressing opioid dependency.

It is common for community pharmacists to receive prescriptions for inappropriate dosages and quantities of initial opioid prescriptions. Pharmacists may also encounter patients who 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 to patients seeking 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 where appropriate, such as non-steroidal anti-inflammatories.

In the wake of a severe shortage of Saskatchewan physicians available to prescribe opioid dependency treatment, Health Canada recently collaborated with the provincial government and regulators to grant Saskatchewan pharmacists a temporary exemption from the CDSA and regulations so that they may prescribe and provide methadone and buprenorphine to patients. We commend Health Canada for taking this step to enable pharmacists to better care for patients left vulnerable by prescriber shortages. We expect this experience will help to demonstrate that, as "practitioners" within the CDSA and with the appropriate provincial regulations, training and safeguards in place, pharmacists could have a meaningful impact on the management and oversight of opioid therapy.

Conclusion

We are pleased that Health Canada is making the necessary regulatory amendments to include tramadol within the CDSA and the NCR as a scheduled narcotic. We appreciate the opportunity to provide feedback on this topic and we look forward to working with Health Canada to further pharmacists' role in helping to resolve 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 gdoucet@pharmacists.ca.

Sincerely,

Glen Doucet
Chief Executive Officer

[1] 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)