SASKATCHEWAN
COLLEGE OF PHARMACY
PROFESSIONALS

SUITE 221A - 1900 ALBERT STREET
REGINA SK S4P 4K8
PHONE: 306-584-2292 FAX: 306-584-9695
E-mail: info@saskpharm.ca

MEMORANDUM

DATE: December 18, 2018

FROM: Saskatchewan College of Pharmacy Professionals (SCPP)

RE: **Exempted Codeine Products (ECPs): Proposed Regulatory Bylaw Amendments: Stakeholder Consultation**

The Saskatchewan College of Pharmacy Professionals (SCPP) is proposing regulatory bylaw amendments to end the storage and sale of Exempted Codeine Products (ECPs) by licensed members (a full ban with a 3-month transition period after the new bylaws are published in The Saskatchewan Gazette). These amendments are being proposed to: enhance the health and safety of the public and members; mitigate the risks associated with the use of ECPs; and respond to increasing concerns over the misuse of ECPs. SCPP is requesting your feedback re: these proposed amendments.

ECPs are found to have numerous health risks, including dependence, to be subtherapeutic at their current dosage levels with risk of acetaminophen toxicity at higher codeine therapeutic or abuse levels, and to place pharmacists at risk of unsafe or difficult situations. Safer nonprescription alternatives exist for the treatment of pain or exhausting, non-productive coughs. Health Canada is in the process of moving towards allowing ECPs to be sold via prescription only and granting authority to pharmacists to prescribe these products. Other provinces and organizations in Canada have publicly expressed their support for prescription-only status for ECPs.

Risks associated with ECPs include: opioid dependence and overdose (even at low doses), slowed heart rate, gastric hemorrhage, renal impairment, life-threatening biochemical imbalances, respiratory depression and arrest, confusion, hallucinations, seizures, stomach pain, nausea, and death. Many ECP preparations contain acetaminophen, which can lead to acetaminophen toxicity and liver failure in individuals who consume large quantities. Opioid dependence resulting from ECPs may also lead to dose escalation and physiological tolerance, which increases the risk of acetaminophen toxicity and migration to more potent opioids, including fentanyl. These side effects negatively impact the health and safety of the public and can lead to increased hospitalizations and public healthcare costs.

Health Canada reported that approximately 600 million low-dose codeine tablets were sold across Canada in 2015, and that more than 500 people entered addiction treatment centers in Ontario alone between 2007 and 2015, with non-prescription codeine as their only problem substance.

Literature indicates that doses of less than 30mg of codeine (ECPs contain < or = 8mg of codeine per solid dosage unit) are subtherapeutic and unlikely to be effective in the treatment of pain or non-productive coughs. The typical effective dose of codeine for the treatment of pain is 15 to 30 mg every 4 hours, with the usual range of 15 to 60mg every 4 hours as needed. The effective dose of codeine to treat a non-productive cough is 10 to 20mg every 4 to 6 hours.

There are safer nonprescription alternatives to ECPs, including acetaminophen and ibuprofen for pain, or dextromethorphan for coughs, which have significantly less risks.

SCPP intends to work with medSask Drug Information Service and Continuing Professional Development for Pharmacy Professionals Unit at the University of Saskatchewan to prepare educational and other supportive resources to help pharmacy professionals transition patients to safer alternative therapies.

Codeine will continue to be available to patients at higher levels by prescription only.

Health Canada is in the process of moving towards allowing ECPs to be sold via prescription only. On September 9, 2017, Health Canada sent a notice to interested stakeholders requesting comments on the potential risks, benefits, and impacts of changes to the regulations under *The Controlled Drugs and Substances Act* that would require all products containing codeine to be sold by prescription only. Subsequent information indicates that Health Canada intends to grant authority for Pharmacists to prescribe these products. Health Canada also no longer recommends the use of ECPs by children under 12, pregnant women, or nursing women (for infant risk) due to the risk of respiratory depression and death.

Other provinces and organizations in Canada have publicly expressed their support for prescription-only status for ECPs. In Manitoba, effective February 1, 2016, all ECPs now require a prescription from a physician, nurse practitioner, dentist or pharmacist.

When ECPs were moved from over-the-counter (OTC) status to prescription-only status in Manitoba, sales of ECPs to pharmacies decreased significantly. This decrease shows that patients who require pain medication have likely been able to effectively move to safer, alternative pain-relief products (such as acetaminophen), and no longer have a need for ECPs. This data also suggests a misuse of ECPs when ECPs are more readily available. In the 12 months from February 2015 to January 2016, 53.4 million units of OTC codeine products were purchased by pharmacies in Manitoba. In the 12 months following this (February 2016 to January 2017) only 3.6 million units of the same products were purchased by pharmacies in Manitoba. This is less than 10% of the purchases from the prior 12 months.

ECPs may also place pharmacists at risk of unsafe or difficult situations. Currently within Saskatchewan, the onus is on the pharmacist to refuse sale for an ECP, where there are reasonable grounds for believing that the drug may be used by a person for other than a recognized medical or dental purpose. Patients may resort to aggression or intimidation when a pharmacist refuses to dispense an ECP.

In summary, SCPP believes that ECPs have numerous health risks, increase costs to the health and safety of the public, and possess very little, if any useful therapeutic purpose that would justify a prescription, regardless of prescriber (physician, nurse practitioner, dentist, pharmacist) given that safer alternatives exist. SCPP also believes that it is inappropriate to shift the prescribing burden and risk of unsafe or difficult situations for ECPs to another prescriber. Therefore, SCPP is proposing regulatory bylaw amendments to end the storage and sale of

ECPs by licensed members (a full ban with a 3-month transition period after the new bylaws are published in The Saskatchewan Gazette, to allow those who are currently using the product to find other, safer alternatives).

This notification is being sent to all SCPP members, pharmacy owners and proprietors, provincial prescriber regulatory and representative organizations, ECP manufacturers, NAPRA and provincial pharmacy regulatory authorities, Health Canada, the Ministry of Health, the Ministry of Justice and law enforcement authorities, national and provincial representative associations, and agencies associated with pain and addictions. Please extend this invitation for feedback to officials within your organization.

Please provide your feedback to Kim Samoila (Kim.Samoila@saskpharm.ca) by January 25, 2019.

Thank you,

Kim Samoila
Policy Analyst

Enclosure