ONTARIO PHARMACISTS ASSOCIATION

Office of the Chief Executive Officer

November 8, 2017

Ms. Michelle Boudreau
Director General
Controlled Substances Directorate
Office of Legislative and Regulatory Affairs
Health Canada
150 Tunney's Pasture Driveway, Main Stats Building
Address Locator: 0302A
Ottawa ON K1A 0K9

VIA EMAIL: ocs_regulatorypolicy-bsc_politiquereglementaire@hc-sc.gc.ca

Dear Ms. Boudreau:

RE: PROPOSED AMENDMENTS TO REGULATIONS TO THE *CONTROLLED DRUGS AND SUBSTANCES ACT*

On behalf of the Ontario Pharmacists Association ('OPA' or the 'Association'), we appreciate the opportunity to comment on Health Canada's consultation on the question of the continued availability of Schedule II codeine-containing preparations without a prescription.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession, and advocating for excellence in practice and patient care. As the largest provincial pharmacy advocacy organization and Canada's largest continuing professional development and drug information provider for pharmacists, OPA represents the views and interests of pharmacy professionals (including pharmacists, pharmacy students, interns and pharmacy technicians) in all practice settings across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practise to their fullest potential, and making them even more accessible to patients, OPA is working to drive the efficiency and effectiveness of the healthcare system.

After considerable deliberation of the risks and benefits related to Schedule II codeine-containing preparations, the Association believes that, in the interest of patient safety and societal impact, there are more risks and negative impacts associated with maintaining the current non-prescription status of these products. Accordingly, **the Ontario Pharmacists Association is completely aligned with the position of the Canadian Pharmacists Association ('CPhA') in its support of proposed amendments to regulations to the *Controlled Drugs and Substances Act* ('CDSA') calling for the sale of all codeine-based preparations pursuant to a prescription from an authorized prescriber, with the added recommendation of including prescriptive authority for pharmacists under the CDSA**. We applaud CPhA for its national leadership on this file and for its thorough commentary on this matter.

Ontario's pharmacists welcome the news that Health Canada is considering changes related to non-prescription codeine products in order to address opioid misuse, abuse and dependency issues. Pharmacists acknowledge and accept their responsibilities and critical roles in addressing the nation's opioid crisis, in serving as gatekeepers of all opioid and controlled/targeted substances, and in protecting the health and safety of the patients they serve every day. Members of OPA have long expressed their concerns regarding:

- The degree of overuse and abuse of non-prescription codeine products;
- The questionable effectiveness of non-prescription codeine products in the treatment of pain, and;
- Potential drug toxicities due to:
    1. Unpredictable pharmacologic effects of codeine given the variable metabolic profiles between patients and erratic endogenous conversions of codeine into morphine; and
    2. Overexposure to the acetaminophen content of some non-prescription codeine products, thereby contributing to liver and chronic kidney disease.

Notwithstanding these concerns, under the current regulatory framework, Canadian pharmacists are limited in their abilities to effectively control and restrict the distribution of Schedule II codeine products. In Ontario, the provincial Narcotic Monitoring System ('NMS') was launched in 2012 as a mechanism to track patient utilization as well as prescribing and dispensing behaviours by health professionals. While this was a welcomed tool for providers and policy makers in understanding utilization patterns for controlled and targeted substances, it was (and still is) unfortunately limited to Schedule I controlled and targeted substances.

To this day, there are no mechanisms other than the tracking of sales data and anecdotal self-reports by patients to help understand patterns associated with the purchase and use of these addictive and potentially harmful Schedule II products. Furthermore, mandating the involvement of pharmacists to either approve or deny the sale of these Schedule II products has been viewed as ineffective specifically with those consumers who are intent on abusing the products. These individuals quickly "learn the system" to know what "story to tell the pharmacist" that would result in approval of the purchase. Alternatively, even with pharmacists' refusal to sell the product, deliberate abusers would simply "move down the street" when turned away by a pharmacist.

On the proposal to move all codeine-containing products to prescription status, the following considerations were explored by the Association:

A. Maintain Schedule II status (no change at all);
B. Maintain Schedule II status, but include data into the monitoring database;
C. Ban all products with 8 mg or less of codeine;
D. Move all codeine-based products to prescription only (current proposal);
E. Move all codeine-based products to prescription only, but include prescriptive authority for pharmacists.

A. Maintain Schedule II status (no change at all) – NOT RECOMMENDED BY OPA

While this is the simplest approach, the challenges, risks and harms that come from it greatly eclipse its benefits and advantages. The current model entrenches codeine misuse and abuse, offers no ability for pharmacists to monitor or effectively restrict sales, and therefore places the user at potentially significant risk due to the lack of integration of sales data into either the provincial NMS or the patient's health record. For these reasons, OPA does not endorse this approach.

B. Maintain Schedule II status but include data into the NMS database – NOT RECOMMENDED BY OPA

Although this approach would allow for the capture by the NMS of sales and utilization data at the individual level, it represents only a modest improvement. Under the current drug scheduling definition:

- *"Schedule II drugs require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, these drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection."*

- *"Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. The sale is controlled in a regulated environment as defined by provincial pharmacy legislation.* [1] *"*

Schedule I drug products demonstrate an increased risk to the patient if used in an unrestricted manner, and the data quoted in the Canada Gazette, Part 1 appears to suggest this risk with Schedule II codeine-containing products:

- *"In 2015, over 600 million low-dose codeine tablets were sold in Canada, the equivalent of 20 tablets for every person living in Canada that year."*

- *"[In] Ontario alone, from 2007 to 2015, an average of 880 individuals per year (representing approximately 2.0% of total admissions per year) who were newly admitted into publicly funded addiction treatment centres indicated non-prescription codeine products as one of their five problem substances. In that same nine-year period, over 500 individuals admitted to these treatment centres stated that non-prescription codeine was their only problem substance."*

These data clearly suggest there are clear and present dangers associated with non-prescription codeine use and that the current model is ineffective in reducing access. While self-care is an important component of our health system, maintaining Schedule II status for abusable products like codeine no longer makes sense. While the inclusion of data into the NMS may help shed some light, it offers no real barrier or improved oversight capabilities. Accordingly, OPA does not endorse this approach.

C. Ban all products with 8 mg or less of codeine – NOT RECOMMENDED BY OPA

It should be noted that there have been statements from several pharmacy and medical professionals that there is no clinical value offered by Schedule II codeine-based products and that they present very real risks of toxicity and/or overexposure related to codeine and/or acetaminophen ingredients. While OPA acknowledges and respects these opinions, we feel that more study needs to be undertaken to substantiate these claims before such a move is contemplated. Therefore, at this time, OPA does not endorse this approach.

D. Move all codeine-based products to prescription only – QUALIFIED SUPPORT BY OPA

Based on the rejected options above, this approach appears to be logical as governments and health providers work to collaborate on tackling the national opioid crisis. However, with such a move in isolation, questions arise about reduced access for patients who are not abusing Schedule II codeine products but are benefiting from them. This effectively limits a patient's access to analgesic options and may add additional strain on

[1] http://napra.ca/sites/default/files/documents/Schedules-Outline.pdf

other health providers – notably physicians and nurse practitioners – in terms of workflow and wait times. Based on these accessibility limitations, OPA offers partial support of this approach.

E. Move all codeine-based products to prescription only but include prescriptive authority for pharmacists – FULL SUPPORT FOR THIS PROPOSAL BY OPA

Insofar as moving all codeine-containing products to prescription status makes logical sense, we cannot ignore the impacts such a move will have of patient access. In view of the desire to have significantly increased oversight on all codeine products along with a minimal impact to those patients who appropriately use and benefit from those currently listed under Schedule II, it is most logical to leverage the work, skills and expertise of the community pharmacists in a way that:

i. Enables the capturing of claims data in real time within the NMS;
ii. Populates the patient's health record to allow for a proper drug utilization review that would include monitoring of adherence; and
iii. Protects reasonable and still timely access to the care, advise, guidance and treatment by a highly trained expert in both medication management and self-care.

In order for this approach to move forward, amendments to the *Controlled Drugs and Substances Act, S.C. 1996, c.19*[2] would be necessary such that pharmacists be included as practitioners authorized to prescribe narcotic and controlled substances. Specifically, the changes (in red font) might read as follows:

> ***2 (1) In this Act, practitioner means a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry, ~~or~~ veterinary medicine or pharmacy, and includes any other person or class of persons prescribed as a practitioner;***

In addition, changes would be recommended for the *New Classes of Practitioners Regulations SOR/2012-230*[3] to the *Controlled Drugs and Substances Act* as follows:

> ***New Classes of Practitioners Prescribed***
>
> ***2. For the purpose of the definition practitioner in subsection 2(1) of the Act, the following classes of persons are prescribed:***
>
> ***(a) midwives;***
>
> ***(b) nurse practitioners; and***
>
> ***(c) podiatrists; and***
>
> ***(d) pharmacists.***

While these OPA-proposed changes may seem, on the surface, to be limited to the matter of moving all codeine-based products to prescription status, they are also important considerations to be made in the broader context of the opioid crisis and discussions on the disposition of medicinal cannabis. At this heightened time where greater oversight of opioids and cannabis is necessary – including consideration of deprescribing and/or opioid tapering services – the skills, training and expertise of pharmacists need to be leveraged to optimize patient care and to ensure opioids are prescribed in accordance with nationally approved pain management guidelines. Based on the immediate and positive impacts of such regulatory changes, **OPA fully endorses this modified version of Health Canada's proposal**.

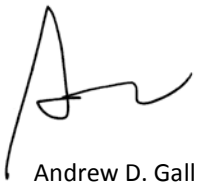
[2] http://laws-lois.justice.gc.ca/eng/acts/C-38.8/
[3] http://laws-lois.justice.gc.ca/eng/regulations/SOR-2012-230/page-1.html

Conclusion

Once again, we applaud Health Canada for taking bold action on the national opioid crisis, and in this particular instance, on its proposal to move all codeine-containing products to prescription status. Along with Health Canada and the Ontario Ministry of Health and Long-Term Care, as well as with the Canadian Pharmacists Association and other critical healthcare stakeholders including the Ontario College of Pharmacists, the Ontario Medical Association, the Ontario Dental Association, the Registered Nurses Association of Ontario and patient groups, we look forward to working collaboratively and collectively to ensure patient safety and access to care remain entrenched in health policy while protecting the public interest from harm resulting from inappropriate or inadvertent use of medications, and particularly opioid therapies.

On behalf of Ontario's pharmacy professionals, we thank Health Canada for the opportunity to provide comments on mechanisms and processes that aim to create a safer health system for Canadians. Should you have any questions related to this submission, I invite you to contact me at your earliest convenience at 416-441-0843 or by email at agall@opatoday.com.

Respectfully submitted,



Andrew D. Gall
Chief Executive Officer

cc: Michael Cavanagh, Chair of the Board of Directors, Ontario Pharmacists Association
Allan H. Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association
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Adele Fifield, Executive Director, National Association of Pharmacy Regulatory Authorities
The Honourable Dr. Eric Hoskins, Minister of Health and Long-Term Care (Ontario)