

## **Summary Safety Review –Opioid-containing cough and cold products - Assessing the potential risk of opioid use disorder and related harms in children and adolescents**

**Product:** Cough and cold products containing opioids (including codeine, hydrocodone or normethadone)

**Potential Safety Issue:** Opioid use disorders and related harms in children and adolescents

### **Key Messages**

- **The growing number of overdoses and harms caused by opioids is a major public health concern in Canada. Cough and cold products containing opioids (including codeine, hydrocodone or normethadone) are authorized for sale in Canada to treat cough and cold symptoms in adults and children.**
- **Health Canada reviewed the risk of opioid use disorder and related harms from these products after the United States Food and Drug Administration (US FDA) advised against using these products in children and adolescents in 2018. Health Canada’s safety review found limited evidence to link opioid-containing cough and cold products with opioid use disorders and related harms in children and adolescents.**
- **These products are linked to other known harms (i.e., breathing problems), and there is limited evidence to support the effectiveness of these products in children and adolescents. There are other products available in Canada to help relieve the symptoms of cough and cold in children.**
- **Therefore, Health Canada, as a precautionary measure, is advising Canadians against the use of these products among children and adolescents under 18 years of age. Health Canada will notify the manufacturers to update the product safety information of opioid-containing cough and cold products to limit the recommended age of use (indication) to adults only, 18 years of age and older. These actions align Canada with US and European practices and product safety information.**
- **Health Canada will also inform Canadians and healthcare professionals about these updates through an Information Update and a Health Product InfoWatch communication.**

### **Overview**

The growing number of overdoses and harms caused by opioids is a major public health concern in Canada. As part of a national strategy to better inform patients on the risks of all prescription opioid-containing products, Health Canada has recently updated the product safety information of these drugs for the risks of problematic drug use. Opioid-related harms have been increasing in Canada in children and adolescents (under 18 years of age), and a published study suggested that early use of opioids is a factor that can lead to opioid-related harms later in life<sup>1</sup>. Individuals with opioid use disorder continue to use opioids, even when they know it is harmful. Opioid-related

harms can include, but are not limited to, the use of an opioid in a way that is not as intended or prescribed.

In light of the current crisis and the approach used by other regulators for similar products, Health Canada reviewed the risks of opioid use disorder and related harms for codeine-, hydrocodone-, and normethadone-containing cough and cold products in children and adolescents.

### **Use in Canada**

- Opioid-containing cough and cold products have been marketed in Canada since the 1950s. There are 3 prescription opioid drugs authorized to treat cough symptoms in Canada: codeine, hydrocodone, and normethadone.
- Low-dose codeine is also available without a prescription in most provinces to treat cough symptoms.
- Currently, codeine products are not recommended for children under 12 years of age, and hydrocodone and normethadone products are not recommended for children under 6 years of age.
- Use of these products in children and adolescents (under 18 years of age) represents a small proportion (4%) of the total opioid cough and cold prescriptions dispensed in Canada.
- The use of prescription opioid-containing cough and cold products has been declining in Canadian children and adolescents over the past 5 years.

### **Safety Review Findings**

- At the time of this review, Health Canada found limited information on reports of opioid use disorder among children and adolescents related to the use of opioid-containing cough medications from either Canadian<sup>a</sup> or international reports.
- Like other opioids, codeine, hydrocodone, and normethadone may lead to opioid use disorder. However, it is often difficult to detect and recognize the signs and symptoms of opioid use disorder in children and adolescents, and these may go unreported.
- A [review done by the Canadian Agency for Drugs and Technologies in Health](#) found a lack of published evidence to support codeine use in children for cough and cold symptoms.
- Health Canada reviewed the published literature, which suggests that adolescents are at a greater risk of problematic opioid use and overdose, while younger children are at a greater risk of accidental poisoning.
- The scientific literature also suggests a possible link between exposure to opioid-containing products in adolescence and a higher risk of problematic opioid use later in life.
- National and provincial data indicate a concerning increase in opioid-related harms in children and adolescents.

## Conclusions and Actions

- While Health Canada’s safety review found limited evidence to link opioid-containing cough and cold products with opioid use disorders in children and adolescents, there is published literature that suggests a possible link between exposure to opioid-containing products in adolescence and a higher risk of opioid-related harms later in life.
- There is limited evidence to support the effectiveness of opioid-containing products to treat cough and cold symptoms in children and adolescents. Additionally, there are other products available in Canada to help relieve the symptoms of cough and cold in children.
- For these reasons, Health Canada is advising Canadians against the use of cough and cold products containing codeine, hydrocodone and normethadone for children and adolescents (under 18 years old).
- Health Canada will publish an Information Update and a [Health Product InfoWatch](#) communication for opioid-containing cough and cold products to inform Canadians, healthcare professionals and patients about the change to the recommended age of use for these products.
- Health Canada will consult with the Drug Safety and Effectiveness Network (DSEN) to study the presence of opioid use disorder and related harms with the use of opioid-containing products. Health Canada continues to monitor side effect information involving opioid-containing cough and cold products, and has requested manufacturers of prescription opioid products to submit risk management plans to track and monitor these risks in the Canadian population. Health Canada will take appropriate and timely action if and when any new health risks are identified.
- Given the broad availability of non-prescription codeine-containing products and their potential for problematic use, Health Canada has initiated a review of all non-prescription codeine-containing products in children and adolescents.

## Additional Information

The analysis that contributed to this safety review included scientific and medical literature, national and provincial surveys, and both Canadian<sup>a</sup> and international<sup>b</sup> reports, and what is known about the use of these drugs both in Canada and internationally.

For additional information, contact the [Marketed Health Products Directorate](#).

## Reference

<sup>1</sup> Miech, Richard et al. “Prescription Opioids in Adolescence and Future Opioid Misuse” *Pediatrics* vol. 136,5 (2015): e1169-77.

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<sup>a</sup> Canadian reports can be accessed through the [Canada Vigilance Online Database](#).

<sup>b</sup> International reports were accessed through the World Health Organization's Adverse Drug Reaction Database