Opioid Warning Sticker and Patient Information Handout Required to Accompany Dispensed Opioids

New Health Canada Regulations

On April 23, 2018, Health Canada announced Regulations Amending the Food and Drug Regulations on opioids that will alter the current opioid dispensing workflow of pharmacists. These changes have been developed and implemented to reduce the risks associated with the post-market use of these products as well as increase patient awareness of the risks associated with these medications, and to encourage safer use.

Mandatory Effective Date

The changes to the regulations will be mandatory and will come into effect October 20, 2018. They will require that an opioid warning sticker be placed on all opioids listed on Part A of the List of Opioids at the time of sale and be accompanied by a patient information handout. Patients who are undergoing opioid substitution therapy may be eligible to receive “carries” for methadone treatment. In this situation, an opioid warning sticker must be placed on each individual methadone bottle dispensed to the patient.

How to Obtain and Use the Warning Sticker and Handout

Pharmacies will be responsible for obtaining the warning sticker and patient information handout and must ensure that they meet the specifications set out in the source document. This means that the sticker and handout cannot be altered from the original. Digital representation of the warning sticker and patient information handout can be found on the Government of Canada’s website.

Both the warning sticker and patient information handout are mandatory to be distributed to patients filling their prescription for the first time and all subsequent refills.

The warning sticker and handout are not required to be placed on over-the-counter opioid preparations containing a low dose of codeine, an opioid, in combination with two or more other medicinal ingredients, as detailed in s.36(1) of the Narcotic Control Regulations, as they are not prescription opioids. The warning sticker and handout are not mandatory when the drug is to be administered under the supervision of a practitioner (ex: a hospital ward for admitted patients, nursing homes, outpatient clinics, emergency departments and outpatient surgery settings) or if the sale of the drug is to a pharmacist or practitioner. Additionally, the warning sticker and handout are not mandatory to be placed on opioids that are specified by qualifiers in Part A of
the List of Opioids which are authorized and used for the treatment of an opioid use disorder and are currently exempt from this requirement.

Health Canada Documents

The following documents provide additional information released by Health Canada that should be reviewed by pharmacists:

- [New regulations to provide better information for patients on the safe use of opioid medications](#)
- [Information Update about the updating of opioid prescription labels through the class labelling initiative](#)
- [Questions and Answers: Prescription Opioids – Sticker and Handout Requirements for Pharmacists and Practitioners](#)