Health Canada Santé Canada

Questions and Answers

Prescription Opioids - Sticker and Handout Requirements for Pharmacists and Practitioners

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Canada

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Foire aux questions : Opioïdes sur ordonnance - Exigences relatives à l'autocollant et à la fiche de renseignements pour les pharmaciens et les praticiens

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Document change log

Date	Change	Location (section, paragraph)	Nature of and/or reason for change
2018/05/02	Initial issuance of guidance	Not applicable	Not applicable
2018/10/01	• Added that opioids which are authorized and used for the treatment of an opioid use disorder are exempt from this requirement, as specified on Part A of the List of Opioids • Provided information on how Health Canada will monitor and enforce compliance with the Regulations	• Section 2: Food and Drug Regulations: Section C.01.005.01 • Section 4: Information for pharmacists and practitioners	New information
2019/02/07	• Provided information related to acceptable minor deviations from the specified format and colour of the warning sticker • Provided definitions for the terms “practitioner” and “sell” • Provided a more detailed description of the exemption to the requirements which is based on the expression: “administered under the supervision of a practitioner” • Clarified the applicability of the requirements based on how often or how much of an opioid is sold • Provided additional clarity on where the warning sticker should be applied • Corrected the coming into force date which was incorrectly specified as October 20, 2018	• Section 3: The warning sticker and patient information handout • Section 4: Information for pharmacists and practitioners	New information/ correction

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1. Introduction

Opioids offer effective pain relief for many patients. Examples of opioids include oxycodone, morphine, hydromorphone, fentanyl and codeine. The strength of opioid medications varies greatly, and nearly all are available through prescription. While effective for pain relief, opioids can pose potential harms including dependence, addiction and overdose that may lead to death. Canadians are using both prescription and illegal opioids at an increased rate. This has contributed to increased rates of opioid addiction and deaths caused by opioid overdose.

Health Canada wants to ensure that patients who need these drugs have access to them, but with the appropriate safeguards. It is important that patients receive clear information about the safe use of opioids and the risks associated with their use. As such, Health Canada has added requirements under the Food and Drug Regulations for a warning sticker and patient information handout to be provided with prescription opioids at the time of sale.

1.1 Policy objectives

To ensure that pharmacists and practitioners comply with the requirements of Part C, Division 1 of the Food and Drug Regulations for drugs on Part A of the List of Opioids, and specifically that pharmacists[1] and practitioners (e.g. physicians, nurse practitioners, etc.):

- apply a warning sticker to the drug package of an opioid which is sold to a patient; and
- provide a patient information handout at the time of selling an opioid drug.

1.2 Scope and application

This document provides guidance on the regulatory requirements specified in Part C, Division 1 of the Food and Drug Regulations regarding prescription labelling requirements for opioid drugs identified in Part A of the List of Opioids.

2. Food and Drug Regulations: Section C.01.005.1

2.1 What do the Regulations require?

Section C.01.005.1 of the Food and Drug Regulations requires that a pharmacist or practitioner selling a Class A opioid (i.e., a drug listed in Part A of the List of Opioids), including one that is compounded by a pharmacist under a prescription or by a practitioner, apply a warning sticker to the drug package and that a patient information handout accompany the drug. Both the warning sticker and the patient information handout must meet the specifications of the source document entitled 'Information for Patients Concerning Opioids' (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout.html#a2), which is published on the Government of Canada's website.

The above requirements do not apply to opioids administered under the supervision of a practitioner (see section 4.6), or if the sale of the drug is to a pharmacist or a practitioner.

These requirements are supplementary to existing prescription drug labelling requirements, which remain in effect.

The above requirements do not apply in specific instances outlined in section 4.5.

2.2 Which prescription opioids require a warning sticker and patient information handout?

All opioids listed on Part A of the List of Opioids (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/list-opioids.html) require a warning sticker and patient information handout, unless there is a qualifier on the List that specifies an exemption. As specified by qualifiers in Part A of the List of Opioids, opioids which are authorized and used for the treatment of an opioid use disorder are currently exempt from this requirement.

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, are also exempt from this requirement as they are not prescription opioids.

2.3 Why is Health Canada mandating the distribution of a specific warning sticker and patient information handout?

Patients receiving prescription opioids need to be provided with clear information about the safe use and risks of these products. Warning stickers and drug information handouts are usually distributed to patients at the discretion of the pharmacist, and could vary from pharmacy to pharmacy. Mandating the distribution of a specific opioid warning sticker and patient information handout will ensure that Canadians receiving prescription opioids are provided with consistent and relevant information in order to better mitigate the risks associated with opioid use.

2.4 When did these new requirements come into effect?

These requirements came into force on October 23, 2018, six months after the registration of the Regulations.

3. The warning sticker and patient information handout

3.1 How was the warning sticker and patient information handout developed?

The content for the sticker and handout was developed by Health Canada based on the recommendations of the Scientific Advisory Panel on Opioids (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/scientific-expert-advisory-panels/opioids.html). Internal focus groups with subject-matter experts were held to ensure the handout content is free of major gaps in serious opioid warnings and precautions and is written in plain language that is as clear as possible. This is consistent with the recently updated Product Monographs for approved opioids in Canada. The sticker also underwent patient user testing to assess the effectiveness and clarity of the content and design.

3.2 What information is included in the warning sticker and patient information handout?

The sticker warns patients about the risks of dependence, addiction and overdose. The patient information handout contains broader information on the safe use of opioids as well as the risks associated with opioid use, including: serious warnings, signs of overdose, possible side effects, and information on safe storage and disposal of opioids. The handout also provides a link to more detailed information on approved prescription opioids, which can be found in their official Canadian Product Monographs.

3.3 Which warning sticker and patient information handout must be used in order to comply with subsection C.01.005.1(1) of the Food and Drug Regulations?

Health Canada has published a source document entitled 'Information for Patients Concerning Opioids' (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout.html#a2), which contains 'Part A: Opioid Warning Sticker' (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout/warning-sticker.html) and 'Part B: Opioid Patient Information Handout' (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout/information-handout.html). This document is available on the Government of Canada website. In order to comply with the Regulations, pharmacists and practitioners must use a sticker and handout that meets the specifications set out in the source document. This means that the sticker and handout must be the same format, color and wording as that which is represented in the source document. With respect to size, the handout has been formatted to print easily on a standard letter-sized or 8.5" x 11" paper. It is recognized that for printing purposes the size of the sticker may need to be adjusted, however, for appropriate readability, the wording on the sticker should not be less than font size 6. Minor deviations from the specified format or colour of the sticker, as represented in the source document, are considered acceptable (e.g., a slightly different shade of yellow as the background colour, yellow colouring inside the inverted triangle symbol in cases where it is not possible to print a white interior, rounding the corners of the sticker instead of having square corners, etc.).

3.4 What is the difference between Health Canada's opioid patient information handout and the Patient Medication Information contained in the Product Monograph?

Health Canada's opioid patient information handout is a one-page document that has been written in plain language and summarizes key safety information for patients that is applicable to prescription opioids. The Patient Medication Information in the Product Monograph (PM) may contain more detailed, product specific information for patients regarding the safe and effective use of a particular drug, including what it is used for, how to take it and other important information.

The PM is a factual, scientific document specific to a particular drug which has been reviewed and approved by Health Canada. The PM describes the properties, indications and conditions of use of the drug and contains any other information that may be required for optimal, safe and effective use of the drug. The Patient Medication Information section of a PM contains information that is written in plain language and is specifically targeted to patients. PMs can be accessed by performing a search in Health Canada's Drug Product Database (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp) or the Drug and Health Product Register (https://hpr-rps.hres.ca/).

4. Information for pharmacists and practitioners

4.1 Who is considered a practitioner?

The term practitioner is defined in section C.01.001 of the Food and Drug Regulations. This definition is also complemented by rules in the Controlled Drugs and Substances Act and the Narcotic Control Regulations around who can prescribe an opioid.

For the purposes of the warning sticker and handout requirements, a practitioner means a person who is entitled (under federal and provincial laws) to treat (e.g., prescribe) patients with a Class A opioid.

4.2 Am I required by law to distribute a warning sticker and patient information handout when I sell an opioid?

Yes. See Section 2.1 above for an explanation of the legal requirements.

Section 2 of the Food and Drugs Act defines the term "sell" as: "offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration". This definition captures the common meaning of the word sell as well as other activities such as dispensing or administering a drug.

4.3 Where can I access Health Canada's warning sticker and patient information handout?

Digital representations of the warning sticker (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout/warning-sticker.html) and patient information handout (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout/information-handout.html) are available on the Government of Canada's website.

4.4 Can I order bulk print copies of the sticker and handout from Health Canada?

No. Health Canada does not distribute print copies of the opioid warning sticker and opioid patient information handout. Health Canada has published digital representations of the sticker and handout online (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-

information-handout.html). Pharmacists and practitioners will be responsible for obtaining or producing copies of the sticker and handout which meet the specifications of the source document.

4.5 In which instances would an opioid not require the sticker and handout?

The sticker and handout are not required to accompany the opioid when the drug is to be administered under the supervision of a practitioner, or when the sale of the drug is to a pharmacist or practitioner.

Additionally, as noted in section 2.2 and specified by qualifiers in Part A of the List of Opioids, (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/list-opioids.html) opioids which are authorized and used for the treatment of an opioid use disorder are currently exempt from this requirement.

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, are also exempt from this requirement as they are not prescription opioids.

4.6 What does the expression “administered under the supervision of a practitioner” mean?

The sticker and handout requirements do not apply when an opioid is administered under the supervision of a practitioner. In the context of these requirements, the expression “administered under the supervision of a practitioner” includes scenarios where the practitioner is directly administering or observing the administration of the opioid, as well as in instances when opioids are administered to a patient by a health care professional, as directed by a practitioner (e.g., in institutional settings such as hospitals, clinics and long-term care facilities). Health care professionals should have medical training in the use and administration of such drugs as well as knowledge about opioid risks.

4.7 Are there exemptions to the requirements based on how often or how much of an opioid is sold?

There is no exemption in the Regulations related to how often or how much of an opioid is sold. This means that a warning sticker must be applied to the drug package and a handout provided every time an opioid is sold (e.g., including for part-fills) and regardless of the quantity of drug sold (e.g., including patients who are granted temporary leave from a hospital and who are dispensed a small supply of the drug for self-administration).

4.8 I regularly distribute the Patient Medication Information section of the Product Monograph to patients receiving prescription opioids. Do I still need to distribute Health Canada’s opioid patient information handout?

Yes. The handout is not interchangeable with the Patient Medication Information section of the Product Monograph. While the handout may supplement existing educational resources that pharmacists and practitioners deem necessary for patients, it cannot be replaced with any other material.

4.9 Where should the warning sticker be applied?

The Regulations require that: "the drug's package has applied to it a warning sticker that meets the specifications set out in the source document". The term 'package' means anything in which the drug is wholly or partially contained, placed or packed. In practice, this would typically mean applying the sticker to the container that is in direct contact with the drug (e.g., medication bottle) – similar to the way that other warning labels are typically applied. For more complex packaging formats, such as blister packs which contain multiple unit doses within a single package, the warning sticker can be applied once to the outer package.

4.10 Can I provide the sticker and handout in either English or French?

Yes. The sticker and handout only need to be provided in one of the official languages, English or French, depending on the patient's choice of language.

4.11 How will Health Canada monitor and enforce compliance with the Regulations?

The Controlled Substances Program (CSP) of the Regulatory Operations and Regions Branch (RORB) of Health Canada conducts inspections in community pharmacies, and is responsible for the compliance promotion and monitoring activities in relation to this regulatory requirement.

Effective October 20, 2018, the compliance and enforcement approach for the opioid warning sticker and patient information handout regulatory requirements will be as follows:

a. Education and Compliance Promotion: Information about the requirements will be distributed to pharmacists during community pharmacy inspections conducted by CSP Inspectors.
b. Compliance Monitoring and Verification: When CSP receives information regarding known or suspected non-compliance, it undertakes compliance within the pharmacy. If a pharmacy is found to be in violation of FDR, C.01.005.1, an observation will be noted in the inspection report. The pharmacy will be given 30 days to explain and/or provide a corrective and preventative action plan (CAPA) in writing to CSP. CAPAs are reviewed by a CSP Inspector to ensure that the action adequately address the violation.
c. Enforcement: CSP will then take enforcement actions, when compliance verification activities have determined ongoing non-compliance despite increased monitoring and oversight to bring the regulated party into compliance. This may result in a non-compliance rating that will need to be addressed with associated corrective measures. CSP will then conduct an inspection, generally within 6 to 12 months, to verify that corrective actions have been taken. In certain circumstances, a non-compliance rating may also result in a referral to the relevant Provincial Pharmacy College.

5. Information for patients

5.1 Do these new requirements mean that my prescription opioid is not safe?

When used appropriately, opioids can help relieve pain and other conditions. But, like all other drugs, opioids have risks associated with their use. Some of these risks are particularly serious and include dependence, addiction, and overdose which can lead to death. Given the risk of opioid-related deaths, Health Canada is implementing measures to improve patient education on the safe use of opioids, and the risks associated with their use. For more information about the safe use of opioids, patients should talk to their doctor or pharmacist.

5.2 Where can I find more information about opioid use?

For more information on the specific opioid(s) you are taking, you should talk to your doctor or pharmacist. You can also get up-to-date information by looking at the official Canadian Product Monograph (PM). PMs are factual, scientific documents that contain information regarding the optimal and safe use of a drug. Health Canada-authorized PMs for some opioid medications are available by searching Health Canada's Drug Product Database (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp).

For general information on opioids, you may consult the Government of Canada's website (https://www.canada.ca/en/health-canada/services/substance-abuse/prescription-drug-abuse/opioids.html).

6. Contact information

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[1] As per the Food and Drug Regulations, pharmacist means a person who (a) is registered or otherwise entitled under the laws of a province to practice pharmacy, and (b) is practicing pharmacy in that province; and practitioner means a person who (a) is entitled under the laws of a province to treat patients with a prescription drug, and (b) is practicing their profession in that province.