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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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON  K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications@hc-sc.gc.ca

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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), 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 4.4), 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.

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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.

### 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.

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 currently 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 do these new requirements come into effect?

These requirements will come into force six months after the regulations are published in Canada Gazette Part II. However, the warning sticker and handout are available on the Government of Canada's website should pharmacists or practitioners wish to distribute them prior to this date.

## 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', 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.

### 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 Am I required by law to distribute a warning sticker and patient information handout?

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

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

Digital representation 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.

### 4.3 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.

### 4.4 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. Situations in which administration under the supervision of a practitioner would usually occur include: a hospital ward for admitted patients, nursing homes, outpatient clinics, emergency departments and outpatient surgery settings.

### 4.5 Do I have to distribute the sticker and handout for all opioid refills?

Yes. The warning sticker and handout must be distributed with prescription opioids included in the List of Opioids (https://canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/list-opioids.html), including for new prescriptions and subsequent refills.

### 4.6 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.

### 4.7 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.

## 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

Bureau of Cardiology, Allergy and Neurological Sciences (BCANS)
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
1600 Scott Street
Holland Cross, Tower B, 2nd Floor
Ottawa, Ontario
K1A 0K9
E-mail: HC.bcans.enquiries.SC@canada.ca