

Newfoundland and Labrador Pharmacy Board Standards of Practice



The Sale of Exempted Codeine Products in Community Pharmacies

September 2016

1) Introduction

Exempted Codeine Products (ECPs) are defined in Section 36 of the Narcotic Control Regulations as follows:

“A preparation containing not more than 8 mg or its equivalent of codeine phosphate per tablet or per unit in other solid form or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in a liquid preparation if

(a) the preparation contains

(i) two additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-half the regular minimum single dose for each such ingredient, or

(ii) three additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-third the regular minimum single dose for each such ingredient; and

(b) there is legibly and conspicuously printed on the inner label and the outer label, as those terms are defined in section A.01.010 of the Food and Drug Regulations, a caution to the following effect: “This preparation contains codeine and should not be administered to children except on the advice of a physician, dentist or nurse practitioner.””

The regulations go on to state that: *“No pharmacist shall sell or provide a preparation referred to in subsection (1) if the pharmacist has reasonable grounds to believe that the preparation is to be used for purposes other than recognized medical or dental purposes.”*

Although ECPs are widely used, there are ongoing concerns regarding the risks associated with their use. Risk of dependence is a primary concern when they are used in adolescents as evidence indicates that early use of opioid analgesics may put them at greater risk of other forms of substance dependence. In addition, a Health Canada review recommends that codeine not be used in patients under 12 years of age because of cases of serious side effects and deaths in children that have been attributed to codeine. Regardless of age, preparations that include acetaminophen are associated with acetaminophen toxicity in individuals who consume large quantities and/or are consuming other acetaminophen products concurrently.

To mitigate these risks, the sale of ECPs is subject to various regulatory requirements.

2) Operational Standards

Before offering ECPs for sale, the pharmacist-in-charge must ensure the following minimum operational standards are met:

- a) *Storage and Security.* In accordance with section 1.6 of the *Standards of Pharmacy Operation – Community Pharmacy* (SOPO-Community), all ECPs must be stored in a safe or cabinet that can be securely locked and is appropriately anchored to the floor and used for the exclusive storage of narcotics and controlled drugs. Such safes or cabinets should be concealed from public view where possible.
- b) *Policies and Procedures.* The pharmacy must develop, maintain and regularly review policies and procedures that outline how to handle requests for ECPs, workflow and documentation requirements, as well as anything else considered relevant to the provision of ECPs.
- c) *Filing and Storage.* In accordance with section 1.6 of the SOPO-Community, records of the provision of ECPs must be filed with prescriptions for other narcotics and controlled drugs in sequence by date and number (either transaction or prescription number).

3) Practice Standards

3.1 Patient Assessment

- a) Only a pharmacist may authorize the sale of an ECP.
- b) Prior to authorizing the sale of an ECP, the pharmacist must personally consult with the patient to determine the appropriateness of the request.

PLEASE NOTE: A pharmacist may decide, after this initial direct consultation with the patient, to allow future pickup by an alternate person but documentation of all sales must be recorded on the correct patient's medication profile.

- c) When considering whether or not the sale of an ECP is appropriate, the pharmacist should take into account:
 - i) The patient's age;
 - ii) Pregnancy and lactation status (if applicable);
 - iii) Relevant allergies and/or sensitivities;
 - iv) Other medical conditions and medications;
 - v) Signs and symptoms of the condition to be treated;
 - vi) Length and severity of present symptoms; and
 - vii) Patient history with ECP usage for the current or other conditions.
- d) The pharmacist is responsible for making reasonable attempts to ensure the patient has not received additional ECPs, or similar prescription/non-prescription medications within an unreasonable time period that would put the patient at risk of additive toxicity. This should include checking the patient's Pharmacy Network profile.
- e) The onus is on the pharmacist to refuse to provide the ECP and refer the patient to another health care provider if it is determined that:
 - i) the condition or symptom(s) are chronic or serious in nature;
 - ii) the ECP will inadequately treat the medical or dental reason for use; or
 - iii) continued use of ECPs is not in the best interests of the patient.

3.2 Package Size Restriction

- a) Sales of ECPs in solid dosage form must be limited to sales of no greater than 100 units.
- b) Sales of ECPs in liquid form must be limited to sales of no greater than 100 mL.
- c) These limitations may only be exceeded pursuant to a prescription from an authorized prescriber.

3.3 Documentation and Labelling Requirements

- a) Each time a pharmacist provides an ECP to a patient; it must be documented in the patient's medication profile in accordance with section 3.5 of the SOPO-Community.
- b) Prior to being supplied to the patient, the ECP must be labelled in accordance with section 3.6 of the SOPO-Community.

3.4 Pharmacist-Patient Consultation

- a) While section 3.8 of the SOPO-Community requires pharmacists to provide education and counselling to patients only on the original filling of a prescription; due to the issues associated with the inappropriate use of ECPs, pharmacists are expected to counsel patients on each and every sale of an ECP.
- b) In addition to the information outlined in section 3.8 of the SOPO-Community, the counselling provided should include warnings concerning the over-use of codeine as well as acetaminophen or ASA.
- c) In addition to verbal counselling, the pharmacist should provide the patient with supplementary written information on codeine use.

4) **Additional Resources**

- a) [Template - Documentation of Pharmacist-Authorized Exempted Codeine Product Requests](#)
- b) Saskatchewan College of Pharmacy Professionals - [Exempted Codeine Products - Patient Information](#)
- c) Saskatchewan College of Pharmacy Professionals - [Exempted Codeine Products - Tools for the Pharmacist](#)

5) **References**

- a) College of Pharmacists of Manitoba - [Exempted Codeine Preparations Practice Direction](#)
- b) Saskatchewan College of Pharmacy Professionals - [Control Over Sales of Exempted Codeine Products Policy Statement](#)