

POSITION STATEMENT

Sale of Exempted Codeine Preparations

Introduction

Although exempted codeine preparationsⁱ 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 (between 12 and 18 years of age) as evidence indicates that early use of opioid analgesics (medical or non-medical) may put them at greater risk of other forms of substance dependence^{ii, iii, iv}. 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^v. 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^{vi, vii}.

To mitigate these risks, the sale of exempted codeine preparations is subject to various regulatory requirements. The sale of these products is restricted by the Controlled Drugs and Substances Act, with the Narcotic Control Regulations allowing them to be provided by a pharmacist to patients upon receipt of a prescription, or without a prescription if the pharmacist determines that the preparation is to be used for recognized medical or dental purposes.

Consistent with this federal legislation, exempted codeine products are listed in Schedule II of the Drug Schedule Regulations^{viii} and are subject to the following additional rules:

- They are only available from a pharmacist;
- They must be kept with an area of the pharmacy to which there is no public access and no opportunity for self-selection;
- The direct involvement and professional intervention from a pharmacist is required prior to the release of the drug to the patient or the patient's agent; and
- They must be sold in accordance with the standards of practice approved by Council.

The Supplemental Standards of Practice for Schedule II and III Drugs further clarifies what is expected of a pharmacist when he or she provides this medication to a patient.

Position

Pharmacists are expected to meet the *Supplemental Standards of Practice for Schedule II and III Drugs* and the *Standards of Practice: General Pharmacy Practice* when providing patients with exempted codeine products.

Procedure

In compliance with the Standards, the pharmacist will, as appropriate:

1. Determine and assess the patient's needs, concerns and health status to develop, implement and monitor the care plan (refer to the NSCP *Standards of Practice: General Pharmacy Practice* - Standard # 1). This includes:
 - gathering relevant information about the patient relative to their need for an exempted codeine preparation,
 - critically evaluating the appropriateness of the patient's request for an exempted codeine preparation, including the quantity being requested, and
 - recognizing and addressing patterns of inappropriate drug use, including refusing to provide the product when appropriate;
2. Educate the patient regarding safe and effective use of the medication, in particular with respect to appropriate dosing and the risks associated with overuse of acetaminophen and codeine on a short and long term basis (refer to NSCP *Standards of Practice: General Pharmacy Practice* - Standard # 4); and
3. Update the patient record with respect to the provision of the medication and related details, as appropriate (refer to NSCP *Standards of Practice: General Pharmacy Practice*, Standard 3). In the interest of collaboration and optimal communication among health care providers, and to mitigate risks of codeine misuse and acetaminophen toxicity, pharmacists are strongly encouraged to record the sale, including the quantity, of exempted codeine preparations sold in the provincial Drug Information System (DIS) and to inform the patient that they are recording the sale, including the reasons for doing so.

ⁱ Narcotic Control Regulations, s. 36 (1)

ⁱⁱⁱ Early-onset drug use and risk for drug dependence problems, *Addict Behav.* 2009 March;34(3):319-322

ⁱⁱⁱ Adolescents' Motivations to Abuse Prescription Medications, *Pediatrics.* 2006 Dec;118(6) 2472-2480

^{iv} Adolescents' Nonmedical Use and Excessive Medical Use of Prescription Medications and the Identification of Substance Use Subgroups, *Addict Behav.* 2013 Nov;38(11): 10.1016

^v *Health Canada Information Update* # RA-33915, June 6, 2013

^{vi} Analgesic Efficacy and Safety of Paracetamol – Codeine Combinations versus Paracetamol Alone: a Systematic Review, *BMJ* 1996; 313:321-5

^{vii} Codeine and Acetaminophen for Pain Relief: A Review of the Clinical Efficacy and Safety, Rapid Response Report:

^{viii} *Drug Schedule Regulations*, Nova Scotia College of Pharmacists