



Control Over Sales of Exempted Codeine Products Policy Statement

Exempted Codeine Products are defined in section 36 of the *Narcotic Control Regulations* as those products containing codeine, which the public may purchase without a prescription. Such products contain not more than 8 mg or its equivalent of codeine phosphate per solid dosage unit, or not more than 20 mg or its equivalent of codeine phosphate per 30 ml in a liquid preparation. In addition, such products must contain two or three additional medicinal ingredients other than a narcotic in therapeutic proportions. The outer package must also bear the full list of all the active ingredients along with a cautionary notification that the product contains codeine, and should not be administered to children except on the advice of a physician or dentist.

The onus is on the PHARMACIST to refuse sale for an Exempted Codeine Product where there are reasonable grounds for believing that the drug may be used by a person for other than a recognized medical or dental purpose. Pursuant to section 36 of the *Narcotic Control Regulations*, the sale may be made only for a bona fide medical or dental reason.

The objectives of this policy statement are to:

1. Provide the pharmacist with tools to control the sale of Exempted Codeine Products.
2. Increase public awareness of the dangers of over-use or **misuse** of these products.
3. Educate the consumer on proper usage of Exempted Codeine Products.

Sections 7 and 8 of Part J of the SCPP Regulatory Bylaws says,

Prohibited Drugs

7 No licensed member shall sell a prohibited drug, nor permit or allow the storage of a prohibited drug in a pharmacy under his management. A prohibited drug includes:

- (a) all Exempted Codeine Products offered for retail sale in a solid dosage form including tablets, capsules, gel caps, and other similar dosage forms in a package size exceeding fifty (50) units, and in liquid preparations exceeding package sizes of one hundred (100) ml.

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Exempted Codeine Products

8 When a person wishes to purchase an Exempted Codeine Product, only a licensed pharmacist, or pharmacist intern under the immediate supervision of a licensed pharmacist, may sell the Exempted Codeine Products. The licensed pharmacist, licensed pharmacy

technician, or intern must document the sale on the patient profile. Except for quantities stated otherwise and pursuant to that authorized by a prescription, the licensed pharmacist, or pharmacist intern under the immediate supervision of a licensed pharmacist, may sell only one (1) consumer package of the Exempted Codeine Product per occasion.

Because of the reported abuse of Exempted Codeine Products and the overwhelming feedback from the membership through a FaxBack survey, Council has adopted the following controls:

1. Size Restriction

- a) Exempted Codeine Products in a solid dosage form including tablets, capsules, gelcaps, and other similar dosage forms will be available for retail sale in package sizes not to exceed fifty (50) dosage units. Products exceeding that quantity are included under Regulatory Bylaw section 7 of Part J, wherein a licensed pharmacist, for nonprescription sales, will not be permitted to stock or sell Exempted Codeine Products exceeding 50 units.
- b) Liquid preparations for Exempted Codeine Products will be limited to 100 ml. Package sizes exceeding 100 ml are included under section 7 of Part J, wherein a licensed pharmacist, for nonprescription sales, will not be permitted to stock or sell Exempted Codeine Products exceeding 100 ml.

2. Sale of Exempted Codeine Products

- a) Only a licensed pharmacist, or a pharmacist intern under the immediate supervision of a licensed pharmacist, may sell an Exempted Codeine Product. The sale of Exempted Codeine Products cannot be delegated to a non-pharmacist. This means the licensed pharmacist or supervised pharmacist intern must **personally** consult with the patient or the patient's agent to determine and assess the appropriateness of the request to self-medicate and make the decision to provide the Exempted Codeine Product. However, the actual purchase, where there is payment for the product, may be delegated to a non-professional.
- b) The licensed pharmacist, or pharmacist intern under the immediate supervision of a licensed pharmacist, may sell only one (1) consumer package of an Exempted Codeine Product (i.e. a maximum of 50 solid dosage units or 100 ml of liquid) at a time to the patient. Multiple sales of the maximum consumer size package available are not permitted. The licensed pharmacist is responsible for ensuring the patient has not purchased additional supplies from another licensed pharmacist within a reasonable time period, dependent upon the medical or dental purpose for use.

3. Documentation

Documentation is a useful tool to educate the patient on the added controls and monitoring of the sale of Exempted Codeine Products. Unfortunately, there are no options currently available to have sales recorded via some type of network system alerting the pharmacist of recent sales to the same individual. Therefore, through an amendment to section 7 of Part J, pharmacists are expected to implement the documentation of all sales of Exempted Codeine Products directly on to the Patient Profile.

- a. The pharmacist must record the sale of an Exempted Codeine Product on the Patient Profile maintained for the person purchasing or for the person on whose behalf the purchase is being made. Documentation would include, as a minimum:
 - i. the date of purchase
 - ii. the product name
 - iii. the quantity sold
- b. The pharmacist is expected to review the profile upon each request to ensure proper compliance, and will communicate with the patient or the patient's agent any usage, which the pharmacist deems problematic.

4. Patient Counselling

The pharmacist is expected to counsel the patient or the patient's agent, in detail, prior to each and every sale of an Exempted Codeine Product. Such counselling must include a warning respecting the effects of over-use of codeine and acetaminophen or ASA. The pharmacist, upon a request for the Exempted Codeine Product, would be responsible for obtaining a disclosure from the patient or their agent, either verbally or in writing, indicating that they have not purchased codeine products either from this or from a different pharmacy within the past 30 day period. This information should be used to determine if the sale should be made. In addition, pharmacists may provide the patient with written supplementary information on codeine use.

5. Prescription Sales

As noted in section 8 of Part J of the Regulatory Bylaws, Exempted Codeine Products, sold pursuant to a prescription, may be dispensed in quantities beyond the limits outlined in section 7 of Part J of the Regulatory Bylaws.

6. Miscellaneous

The pharmacist may charge a reasonable fee for documentation and counselling.