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Member Organization of the National Association of Pharmacy Regulatory Authorities (NAPRA)

GUIDELINES FOR THE SUPPLY OF EXEMPTED CODEINE PRODUCTS

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INTRODUCTION

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. The above products do not contain more than 8 mgs or its equivalent of codeine phosphate per solid dosage unit, or more than 20 mgs or its equivalent of codeine phosphate per 30 ml in a liquid preparation.

These products must contain two or three additional medicinal ingredients other than a narcotic in therapeutic amounts. The product's outer package must display the full list of all the active ingredients along with a cautionary notification that the product contains codeine, and thus should not be administered to children except on the advice of a physician or dentist.

There are a number of conditions that govern the sale, by pharmacists, of non-prescription codeine-containing products to the public. The above products must be retained within an area of the pharmacy where there is no public access and no opportunity for self-selection. Even though these Schedule II drugs are less strictly regulated, they do require professional intervention from the pharmacist at the point of sale and possibly referral to a physician.

In Canada, codeine is the only opioid that can be purchased without a prescription. These Exempted Codeine Products, however, cannot be purchased without a prescription in the United States. The fact that these codeine-containing products can be obtained without a prescription in Canada is a major contributing factor for Canada being one of the leading users of codeine in the world.

It is both the responsibility and duty of the PHARMACIST to refuse the sale of these Exempted Codeine Products 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. In accordance with Section 36 of the Narcotic Control Regulations, the sale may be made only for a legitimate medical or dental reason.

Because of codeine's potential for abuse, and the potential danger to the patient from inappropriate use of other ingredients contained in Exempted Codeine Products, pharmacists have asked for guidelines to assist them in the of the sale of Exempted Codeine Products.

Guidelines for pharmacist authorized sale of Exempted Codeine Products are described below:

1. Package Size Restriction

- Exempted Codeine Products in solid dosage form including tablets, capsules, gelcaps, and other similar dosage forms should only be available for retail sale in package sizes no greater than one hundred (100) dosage units. Products exceeding that quantity should not be permitted to be stocked or sold by a pharmacist for non-prescription sales.
- Liquid preparations for Exempted Codeine Products should be limited to 100 ml. Package sizes greater than 100 ml should not be permitted to be stocked or sold by a pharmacist for non-prescription sales.

2. Documentation of Supply to Patient

There are no options currently available to have the supply to patient recorded by a network system that could alert the pharmacist of recent sales to the same individual. Until a network system is in place, pharmacists must ensure they monitor sales of these products in their own pharmacies. The pharmacist must make the decision to recommend the treatment of symptoms based on interaction with the patient.

a. Patient Profile

Once the pharmacist determines the appropriateness of the request to self-medicate, he/she should document the transaction on the patient's medication profile or other suitable recording system. A pharmacist may decide to allow pickup by an alternate person but the documentation must include the patient's name as well as their "agent".

Documentation should provide the following transaction information:

- i) date of supply;
- ii) brand name of drug, or generic name of the drug and name of manufacturer;
- iii) quantity of the drug;
- iv) identification of the pharmacy;
- v) initials of licensed pharmacist authorizing supply.

b. Retention of documentation

Each pharmacy shall ensure that transaction information regarding pharmacist authorized supply of Exempted Codeine Products is retained for 2 years from the date of entry.

3. Patient Counselling

The pharmacist should counsel the patient, in detail, prior to each and every sale of an Exempted Codeine Product. The counselling should include a warning concerning the effects of over-use of codeine and acetaminophen or ASA. The pharmacist, upon a request for an Exempted Codeine Product, must be responsible for obtaining a disclosure from the patient, either verbally or in writing, indicating whether they have obtained codeine containing products from any other pharmacy within the past thirty (30) days. In addition to this counselling, the pharmacist should provide the patient with written supplementary information on codeine use.

4. Supply

Only a pharmacist may authorize supply of an Exempted Codeine Product. The supply of such a product cannot be delegated to a non-professional. The pharmacist must personally consult with the patient to determine the appropriateness of the request to self-medicate and then make the decision whether to dispense the Exempted Codeine Product. However, the actual purchase, where there is a payment for the product, may be delegated to a non-professional.

A pharmacist should not make multiple supplies of the maximum consumer size package available at a time to a patient, unless authorized by a prescription. The pharmacist is encouraged to ensure the patient has not purchased additional supplies within a reasonable time period, dependent upon the medical or dental reason for use.

Bibliography

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