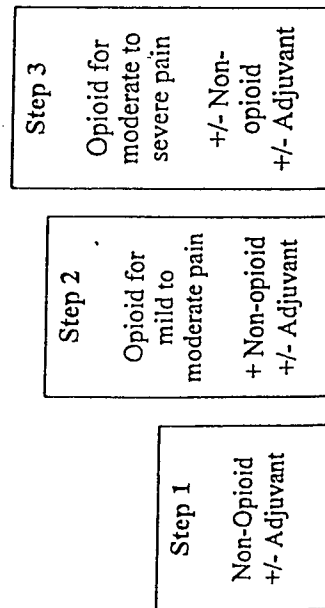


## 5. REBOUND HEADACHES

Often, the use of OTC medications may actually make headaches worse if the medication used to treat the headache is consumed too often. Rebound headaches occur when the patient stops taking the pain reliever for any period of time. Basically, the body is demanding its "fix". Warning signs for rebound headaches include:

- taking an Exempted Codeine Product to treat a migraine or tension headache more than two or three days a week on a regular basis;
- taking analgesics more than a couple of times a week makes one more vulnerable to having the headache escalate in frequency and may become more difficult to treat;
- the patient carries a stash of pain relievers at all times, including purse, car, office, gym bag, etc.;
- sleeping in on weekends results in waking up with a pounding headache;
- the patient has a headache almost daily, or gets one at the slightest mentally or physically stressful situation;
- use of the pain reliever does not eliminate the pain, but simply takes the edge off.

## 6. THE WORLD HEALTH ORGANIZATION "Stepped Approach to Pain Management"

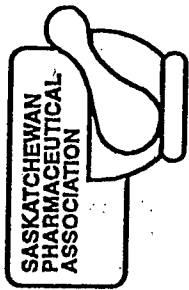


## 7. GOALS OF PAIN TREATMENT

- Reduce medication misuse and invasive medical procedures
- Maximize and maintain physical activity
- Return patient to productive activity at home, socially, and/or work
- Increase patients' ability to manage their own pain and related problems
- Reduce subjective pain intensity
- Reduce or eliminate the use of health care services for primary pain complaint
- Minimize treatment cost without sacrificing quality of care

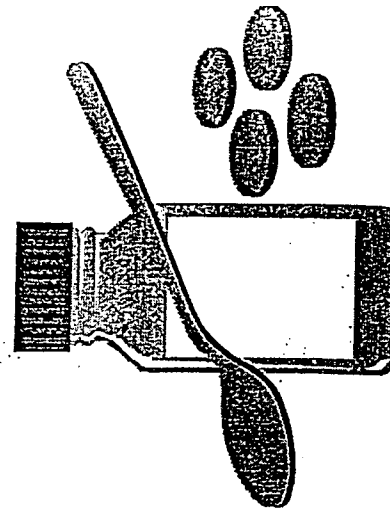
## 8. SCREENING TOOL... SAMPLE QUESTIONS TO ASK

- What condition(s) are you treating?
- Are you self-medicating or purchasing upon the advise of a practitioner?
- Have you tried alternative treatment (i.e.: rest, ice, heat, NSAIDS, etc.)?
- How long have you experienced this condition?
- Have you experienced this same condition before?
- How did you previously treat the condition?
- Was the treatment regime successful?
- Do you understand the potential side effects of Exempted Codeine Products?
- Are you allergic to ASA, Acetaminophen, Codeine or Caffeine?
- When did you last purchase an Exempted Codeine Product?
- If using for a headache, do you understand the phenomenon of rebound headaches?
- Are you concurrently taking other nonprescription medications? What are their names?
- Are you presently taking prescription drugs? What are their names?



# THE EXEMPTED CODEINE PRODUCTS BYLAW

# TOOLS FOR THE PHARMACIST



## 1. PREAMBLE

Per capita, Canada is one of the world leaders in the consumption of codeine. A contributing factor is the availability of codeine as a nonprescription medication. Over the years, health professionals have recognized the abuse potential of codeine. Many medical and pharmacy provincial jurisdictions have developed Triplicate Prescription Programs in an attempt to reduce the abuse and diversion of certain potentially habit forming medications, including codeine products. This captures information of those individuals overusing prescription codeine. However, there is no formal mechanism to assist the pharmacist with monitoring, counselling, or educating the patient respecting the nonprescription use of codeine.

## 2. SALES RESTRICTIONS OF EXEMPTED CODEINE PRODUCTS

In Saskatchewan, effective, March 1, 1998, the Minister of Health approved the following bylaw:

*"No pharmacist 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:*

- 1) Talwin Compound-50, or any substance containing, or represented as containing the same formulation;*
- 2) All Exempted Codeine Products offered for retail sale in a solid dosage form including tablets, capsules, gels, and other similar dosage forms in a package size exceeding fifty (50) units, and in liquid preparations exceeding package sizes of one hundred (100) mls."*

In addition, the following bylaw places the onus of sale directly onto the pharmacist:

*"When a person wishes to purchase an Exempted Codeine Product, only a pharmacist, or an apprentice under the immediate supervision of a pharmacist, may sell the Exempted Codeine Product. Except for quantities stated otherwise, and pursuant to that authorized by a prescription, the pharmacist, or apprentice under the immediate supervision of a pharmacist, may sell only one (1) consumer package of the Exempted Codeine Product per occasion."*

## 3. RATIONALE FOR THE USE OF COMBINATION ANALGESICS

Nonprescription Exempted Codeine Products are intended for acute episodes requiring short-term relief of mild to moderate pain. A physician should assess longer term or more potent pain relief. Larger quantities can be dispensed only when prescribed by a physician.

While it may appear to be logical to combine a narcotic with another analgesic with a different mechanism of action, there is little clinical evidence to support the efficacy of a combination of ASA or Acetaminophen with caffeine and codeine. In order to achieve any extra analgesic effect provided by these drug combinations, at least 60 mg of codeine is required. The effectiveness of 8 mg of codeine in combination with ASA or Acetaminophen and caffeine appears to be minimal. Little evidence exists to demonstrate that combinations of two analgesics are superior to optimal dosing with either agent alone. Studies have demonstrated that caffeine can enhance the analgesic effects of ASA and Acetaminophen.

Not only is there a concern about the overuse of codeine, but also the toxic effect of an excessive amount of either Acetaminophen or Acetylsalicylic Acid to which the patient is subjected while consuming these products. Products contain 300 mg to 500 mg of Acetaminophen or Acetylsalicylic Acid per solid dosage form.

## 4. OVERUSE DANGERS

### ACETAMINOPHEN:

In therapeutic doses, Acetaminophen is relatively non-toxic. However, chronic use of large doses may produce significant toxicity. Chronic use of high doses (i.e. greater than 4 gm daily for several weeks in adults, or 150 mg/kg/day for 2-4 days in children) have been associated with hepatotoxicity. Nephropathy has also been reported following consumption of large amounts of Acetaminophen. Long term use, to a maximum of 2.6gm per day should only be considered if the patient is under the active care of a physician.

### ACETYSALICYLIC ACID:

Chronic ASA intoxication may result from high doses or prolonged therapy with high doses. Tinnitus and hearing loss are the most frequent signs of chronic intoxication. Other manifestations include damage to the stomach lining, dimness of vision, headache, dizziness, mental confusion, drowsiness, sweating, hyperventilation, thirst, tachycardia, nausea, vomiting, and sometimes diarrhea may occur. Symptoms of acute toxicity may occur with doses greater than 150 mg/kg.

### CODEINE:

Codeine causes constipation, drowsiness or sedation and respiratory depression. Care must be observed with the use of codeine, as there is the potential of tolerance and addiction. Although codeine dependence has a relatively lower incidence and is less intense than with more potent narcotics, it is nonetheless well documented.

### CAFFEINE:

Caffeine has long been known to have stimulant properties. Caffeine intake 30-60 minutes before bedtime significantly delays sleep onset, decreases total sleep time, alters normal sleep patterns, and decreases the subjective quality of sleep.

Consumption of more than 1 gram per day of caffeine can produce both pharmacological:

- irritability, agitation, anxiety, reflex hyperexcitability, dizziness, vertigo, insomnia, occasional muscle twitching, ringing in the ears, and visual flashes of light;

and non-central nervous system symptoms:

- palpitations, extrasystoles, tachycardia, arrhythmia, flushing, nausea, vomiting, diarrhea, epigastric pain, dehydration, fever, and edema.



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