3 November, 2016

COLLEGE OF PHYSICIANS AND SURGEONS
OF SASKATCHEWAN
TO COUNCIL

FROM: Registrar

SUBJECT: Request for Support to Move Non-Prescription Codeine Products to Prescription Only Status

For Your Decision
MEMORANDUM

DATE: 3 November, 2016
TO: Council
FROM: Registrar
RE: Request from the Canadian Health Professionals for Evidence Based Drug Policy to Move Non Prescription Codeine Products to Prescription Only Status

Decision

Council will need to decide whether it would like to send a letter of support to move non-prescription codeine products to prescription only status.

Background

Dr. Beggs in his capacity as President received a letter from Mr. Brett Sunku, a pharmacist representing Canadian Health Professionals for Evidence Based Drug Policy. Mr. Sunku is seeking the College of Physicians and Surgeons’ support to move non-prescription codeine products to prescription only status.

Mr. Sunku has provided the evidence to support the proposal and lists the evidence as follows:

1. Non-prescription codeine products are no more effective and have more risks than over the counter alternatives (e.g. acetaminophen, ibuprofen, naproxen).
2. Codeine is an opioid, prone to abuse and addiction. There is clear documented misuse at even low doses in non-prescription products.
3. Due to wide inter-individual variability in codeine metabolism, a significant number of individuals are at risk of sedation, respiratory depression, and death at every at risk.
4. Pharmacists have proven unwilling or unable to properly regulate the sale of non-prescription codeine products.
5. Non-prescription codeine products often contain acetaminophen and the resulting acetaminophen overdoses resulting from overuse is significant and incurs major costs to our public healthcare system.
6. Jurisdictions similar to Canada are also responding with up-regulation of codeine containing products.
7. There are no direct public costs to removing these drugs beside the legislative costs of amending the Controlled Drugs and Substances Act. Patient can easily be transitioned to other non-prescription alternatives.

Mr. Sunku also provides a copy of an open letter and policy briefing note that is currently being reviewed by Prime Minister Justin Trudeau and Minister of Health Jane Philpott. Mr. Sunku and colleagues call upon the Minister of Health “to have these ineffective and unsafe non-prescription codeine products removed from pharmacy shelves. Canadians, especially in the midst of the current opioid crisis, expect that strict limits are in place for all opioids, including codeine”.

cc:...
From: "Brett Sunku" <brett.sunku@gmail.com>
To: "Gareau, Caro CPSS" <caro.gareau@cps.sk.ca>
Subject: Canadian Health Professionals for Evidence-Based Drug Policy: Request for Support from Allan Beggs

Dear President Allan Beggs,

My name is Brett Sunku, and I’m a pharmacist representing Canadian Health Professionals for Evidence-Based Drug Policy. I would like the College of Physicians and Surgeons of Saskatchewan’s support to move non-prescription codeine products to prescription only status.

Throughout my career as a pharmacist, I’ve felt powerless to prevent abuse of codeine and I have watched numerous colleagues sell these risky products with no questions asked. This problem is societally pervasive and often goes unrecognized by policymakers and regulators, such that recent investigative journalism has shed a light on addiction to non-prescription codeine, and the lack of action taken by provincial pharmacy regulatory colleges to address substandard actions by pharmacists.

Frankly, the evidence to support our proposal cannot be refuted:

1. Non-prescription codeine products are no more effective and have more risks than over-the-counter alternatives (e.g., acetaminophen, ibuprofen, naproxen).

2. Codeine is an opioid, prone to abuse and addiction. There is clear documented misuse at even low doses in non-prescription products.

3. Due to wide inter-individual variability in codeine metabolism, a significant number of individuals are at risk of sedation, respiratory depression, and death at even recommended doses. Pharmacists cannot identify these individuals who are genetically at risk.

4. Pharmacists have proven unwilling or unable to properly regulate the sale of non-prescription codeine products.

5. Non-prescription codeine products often contain acetaminophen and the resulting acetaminophen overdoses resulting from overuse is significant and incurs major costs to our public healthcare system.

6. Jurisdictions similar to Canada are also responding with up-regulation of codeine containing products.

7. There are no direct public costs to removing these drugs beside the legislative costs of amending the Controlled Drugs and Substances Act. Patient can easily be transitioned to other non-prescription alternatives.

I would ask that you kindly review the attached open letter and policy briefing note that are also currently being reviewed by Prime Minister Justin Trudeau and Minister of Health Jane Philpott.
With your support, President Beggs, we can more strictly regulate harmful, and ineffective opioid containing drugs that are directly harming the Canadian public.

Please reply with your formal statement of support or call me at the number below. Your time and attention is greatly appreciated.

Sincerely,

Brett Sunku
Canadian Health Professionals for Evidence-Based Drug Policy
brett.sunku@gmail.com
(778) 938-1575
An Open Letter to the Honorable Jane Philpott, Minister of Health & Provincial College of Pharmacists Registrars

The Toronto Star poignantly recounts a Toronto man’s dependency to non-prescription codeine, starting at the age of 16. Getting high daily, he would extract codeine from up to 80 pills and dissolve it in a bitter, cloudy drink. He described how he couldn't endure a friend’s wedding without his “pill juice”. After abusing non-prescription codeine on and off for more than a decade, and always acquiring it legally, he finally got help for his opioid addiction. He landed in the hospital, lost a long-term girlfriend and isolated himself from family and peers. He is now taking methadone, perhaps for the rest of his life.

The current regulation of non-prescription codeine, also known as Exempted Codeine Products, is needlessly harming the public and is contributing to Canada’s opioid problem. The legislation allowing the sale of these products without a prescription must be changed.

By consuming an ECP, a patient is at risk for opioid addiction, overdose, and hospitalization.1,2 Appallingly, there is evidence that ECPs is no more effective than safer, over-the-counter alternatives.3-5 begging the question: why are these products even on the market?

At this time, there is little stopping an individual or groups of individuals from frequenting multiple pharmacies to purchase large quantities of ECPs, especially as not all provinces require the recording of ECP sales in their provincial prescription monitoring programs.6 Pharmacist assessment remains the only check prior to selling an ECP. In practice, all too often, this check can be completely absent, as was recently demonstrated by investigative journalists.6,7

Having pharmacists as the gateway to access ECPs is clearly not working. One pharmacist can refuse to sell an ECP, but that doesn’t prevent the patient from walking across the street to the next pharmacy. Patients can easily bypass the pharmacist assessment with pre-rehearsed scripts and they may resort to aggression or intimidation even if a pharmacist is vigilant in their assessment.8

We are a group of Canadian pharmacists and physicians who are deeply concerned with the misuse of ECPs. We welcome the February 2016 decision of the Manitoba College of Pharmacists to remove these products from their non-prescription status.9 In addition, we fully support the plans of the Honorable Jane Philpott, Minister of Health to introduce regulatory changes to move all non-prescription codeine products to prescription only status.10 We are saddened with the reporting in “Canada’s Invisible Codeine Problem”, published recently in the Toronto Star,9 and by CBC Marketplace which demonstrate, across Canada, the accessibility of the only non-prescription opioid.7 These works of journalism have confirmed our suspicions and the realities that many community pharmacists encounter on a daily basis.

- 1 -

We read stories like the ones above with a heavy heart, knowing that they may involve our own professional practice. We fear that the public is losing faith in the ability of our regulatory bodies to protect patient safety, as these stories are completely preventable.

We recommend that the following occur to address non-prescription codeine abuse.

1. Require that all codeine containing products require a prescription. This would be accomplished by repealing Section 36 from the Narcotic Control Regulations of the Controlled Drug and Substances Act.11

2. Recording the sale of any codeine product in a single unified provincial electronic health record, that is accessible to pharmacists, physicians, and other authorized prescribers, at the point of care.

Such changes have already taken place in Australia for certain codeine preparations and are congruent with the best scientific evidence available, as discussed below.12,13

**Exempted Codeine Products**

- Contain the opioid codeine and do not require a prescription for purchase
- Contain 8 mg of codeine per tablet or 20 mg of codeine per 30 mL of liquid product 11 (see Appendix I for a list of products)
- Combined with 2-3 additional non-controlled substances in therapeutic proportions
- Risks of codeine are the same as any other opioid, such as fentanyl, and they include sedation, addiction, respiratory depression, and death
- Addiction, resulting from euphoric side effects of codeine or uncontrolled pain, often leads to dose escalation and physiological tolerance which risks migration to potent opioids such as heroin or fentanyl 1,2,6,14
- One bottle of 200 tablets of non-prescription Tylenol No.1 or 222*s contains 1600 mg of codeine, more than enough to harm a regular-sized adult

**Healthcare Vs. Business interests**

As most modifications to packaging and quantities in other jurisdictions have been ineffective at curbing misuse,15 the concentration of policymakers has been on the regulation surrounding sale.5 The onus is currently on the pharmacist to refuse sale of ECPs if suspecting misuse. They are the only barrier and that barrier is ineffective. It is proving unrealistic to expect pharmacists to properly regulate the sale of ECPs. There are three major limitations:

- Business interests to sell more product.
- Insufficient human resource allotment for interviewing patients in busy pharmacies.16
- Retail pharmacists are not positioned to recognize nor assess opioid abuse and addiction.
ECPs are Ineffective at Suggested Dosing

ECPs have a too low dose a of codeine; the minimum therapeutic dose of codeine is 30 mg in adults. One can only attain a therapeutic dose by taking higher than recommended doses of non-prescription codeine products, thus overdosing on the other drugs within the preparation, such as acetaminophen. These formulations attempt to leverage the risk of overdose of the non-narcotic components in order to prevent dose-escalation of codeine. Unfortunately, drug abusers often overdose without regard to negative consequences.

Pharmacists aren’t Well Positioned to Address Opioid Misuse

The abuse potential of opioids is well documented, this applies to ECPs as well. A cross-sectional study found that among those reporting codeine use, 15.1% misused it and/or used it for a non-medical reason. Unfortunately, the majority of those addicted to non-prescription codeine begin using the products for a legitimate medical reason.

At most a pharmacist can only refuse to sell and recommend treatment, they cannot prevent a patient from attempting to acquire ECPs from another pharmacy. In many cases, patients avoid discussions about treatment because of fear of their addiction being recorded.

Hazards with Codeine, in addition to Addiction

More than 2% of Canadians convert codeine to morphine, its active form, at an accelerated rate: meaning approximately 700,000 Canadians can overdose even at low doses. Health Canada no longer recommends use in children under 12 years as well as pregnant or nursing women (for infant risk) due to risk of respiratory depression and death. This has led to experts questioning if codeine should be phased out altogether due to its risks and weak painkilling effect.

Codeine Use Requires Physician Oversight

There are not currently any therapeutic guidelines that recommend codeine use without physician oversight. Current evidence indicates that the only conditions that have shown clinical response to codeine are chronic pain due to hip osteoarthritis and acute postoperative pain: the effective doses for these conditions being 30 mg and 60 mg respectively; both are prescription strengths.

The director of the Addiction Medicine and Toxicology Service in Melbourne, Dr. Michael McDonough, has suggested that nobody should have access to codeine without a prescription.

There are Safer Alternatives to ECPs

Current clinical evidence demonstrates that ECP painkillers do not show a benefit over conventional over-the-counter pain medicines such as acetaminophen.
Acetaminophen Overdose

Acetaminophen is the leading cause of acute liver failure in Canada.27

In order for a patient to attain a therapeutic dose of codeine (30 mg) from an ECP (8 mg), one would need to take at least 4 tablets. In the case of Tylenol® No.1, the most commonly purchased ECP, overdose of acetaminophen can cause acute drug induced liver failure, ultimately contributing to shortened lifespans and a burden on the public health system.28,29 According to a recent Health Canada safety review, acetaminophen-codeine combination products are often directly responsible for acetaminophen overdoses and acute liver failure.27 In addition, many experts have called for a lower daily dose limit of 2600 mg of acetaminophen, a dose easily surpassed in ECP abuse.

Actions Taken in Other Jurisdictions

Australia’s Therapeutic Goods Administration is reviewing their non-prescription codeine products.12,13 Policymakers see the need for review amid widespread outcry against codeine deaths.26,30

The College of Physicians and Surgeons in Alberta and British Columbia have also added scrutiny to the prescribing of opioids.31,32 This is in response to their widespread opioid abuse epidemic. This represents a progressive approach to protecting the Canadian public from the risks of opioids. We believe that amending the Narcotic Control Regulations is the best way to solve the problem by setting a national standard for all codeine containing products.

Conclusion

Non-prescription codeine provides a false sense of security.21 But as we, and others, have articulated, ECPs have tremendous risk and no evidence for efficacy.

We call upon the Minister of Health to have these ineffective and unsafe non-prescription codeine products removed from pharmacy shelves. Canadians, especially in the midst of the current opioid crisis, expect that strict limits are in place for all opioids, including codeine.

Sincerely,

Brett Sunku, BPharm, RPh (BC)  
Joseph Blais, BScPharm, ACPR, BCPS (AB)  
Gurneil Parmar, BPharm, RPh (BC)  
Kevin Wang, BPharm, RPh (BC)  
Mohamed Hasanine, BPharm, RPh (BC)  
Lauren Marina Zolpys, MD, FRCPC (BC)  
Philippe Boilard, BPharm, RPh (AB)  
Kody Lee, BPharm student (AB)  
Kamal Alhallak, BPharm, RPh (AB)  
Muffadal Shamshuddin, BPharm, RPh (BC)  
Edward Fang, BPharm, RPh (BC)
## Appendix I - Exempted Codeine Products sold in Canada

<table>
<thead>
<tr>
<th>Representative Brand Product</th>
<th>Ingredients and strength</th>
<th>DIN</th>
</tr>
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<tbody>
<tr>
<td>TYLENOL® NO. 1</td>
<td>Codeine 8 mg Acetaminophen 300 mg Caffeine 15 mg</td>
<td>02181061</td>
</tr>
<tr>
<td>222® TABLETS*</td>
<td>Codeine 8 mg Acetylsalicylic acid 375 mg Caffeine 15 mg</td>
<td>00108162</td>
</tr>
<tr>
<td>CALMYLIN®</td>
<td>Codeine 3.33 mg/5 mL Ammonium 125 mg/5 mL Diphenhydramine 12.5 mg/5 mL</td>
<td>00535230</td>
</tr>
<tr>
<td>BENYLIN® CODEINE*</td>
<td>Codeine 3.33 mg/5 mL Pseudoephedrine 30 mg/5 mL Guaifenesin 100 mg/5 mL</td>
<td>01944703</td>
</tr>
<tr>
<td>ACETAZONE FORTE-8®</td>
<td>Codeine 8 mg Acetaminophen 300 mg Chlorzoxazone 250 mg</td>
<td>00834319</td>
</tr>
<tr>
<td>MERSYNDOL®</td>
<td>Codeine 8 mg Acetaminophen 325 mg Doxylamine 5 mg</td>
<td>02047667</td>
</tr>
<tr>
<td>ROBAXISAL® C-1/8*</td>
<td>Codeine 8 mg Acetylsalicylic acid 325 mg Methocarbamol 400 mg</td>
<td>01934775</td>
</tr>
</tbody>
</table>

Numerous generic versions exist and are marketed under the following labels: Exact®, Equate®, Stanley®, Pharmasave®, Life®, Praxis®, Preferred®, Rexall® Wampole®, and Rougier®

*Brand product no longer marketed in Canada, but generic versions are available.
References


For the Honourable Jane Philpott, The Federal Minister of Health & The House of Commons Standing Committee on Health (HESA)

August 31, 2016

POLICY BRIEF

Combating codeine misuse: Repeal of Section 36 from the Narcotic Control Regulations of the Controlled Drug and Substances Act.

Brett Sunku R.Ph., BPharm & Joseph Blais BScPharm, ACPR, BCPS
Canadian Health Professionals for Evidence-Based Drug Policy
To: The Federal Health Minister and The Standing Committee on Health  
From: Canadian Health Professionals for Evidence-Based Drug Policy  
Subject: Combating codeine misuse: Repeal of Section 36 from the Narcotic Control Regulations of the Controlled Drug and Substances Act.

Non-prescription access to codeine is contributing to Canada’s opioid problem. In practice, the pharmacy profession has proven unable to prevent misuse of these products. Access to these drugs without physician oversight risks opioid addiction, overdose, and hospitalization. In addition, current clinical evidence demonstrates that these products have no benefit over safer, over-the-counter pain-killers. Removing section 36 from the Narcotic Control Regulations stands to prevent harm to Canadians without reducing access and quality of care.

**Codeine**

- An opioid analgesic/antitussive in the same family as fentanyl that carries abuse potential and safety concerns.
- At doses above 8mg per tablet, its prescriptive requirements are controlled by federal and provincial regulations due to its abuse potential.
- Adverse effects include sedation, addiction, respiratory depression and death.
- Addiction, resulting from euphoric side effects or uncontrolled pain, often leads to dose escalation and migration to more potent opiates (such as heroin or fentanyl).

Exempted Codeine Products (ECPs) are available without a prescription. Defined in the Narcotic Control Regulations (see Appendix I), ECPs contain no more than 8mg of codeine per tablet, combined with two or three additional non-controlled substances in therapeutic proportions. This is a subtherapeutic dose of codeine; the minimum effective dose in adults is 30mg. One can only attain a therapeutic dose by taking higher than recommended doses (4 tablets) and overdosing on the other components within the preparation. These products attempt to leverage the risk of overdose of the non-narcotic components in order to prevent dose-escalation of codeine.

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The most commonly used ECPs are combined with acetaminophen (Tylenol No.1®) while others contain ASA (222s®), antihistamines or muscle relaxants. These additional drugs each have unique risks as well as safety concerns and overdose can lead to hospitalization.9,10 In addition, codeine itself is a drug with safety hazards, besides addiction risk. For a significant portion of the population, they metabolize codeine dysfunctionally and risk overdose even from regular doses (representing more than 700,000 Canadians).11,12

As not all pharmacies track sales of ECPs in their provincial pharmacy databases, patients can visit multiple pharmacies, acquiring large amounts from each.2 One 200 tablet bottle contains 1600 mg of codeine, equivalent to 890µg of IV fentanyl (enough to harm a regular adult).13

Considerations

Most studies concerning this subject come from Australia, where many codeine products have already been removed from non-prescription designations.14 There, nearly 1 in 5 non-prescription codeine users were identified as dependent with two thirds of this population overdosing regularly.1 Previous modifications of regulation (explicit labelling, limiting the size of packages) while maintaining product non-prescription designation has not proven to reduce misuse.15

Removal of clause 36 from the Narcotic Control Regulations would result in the requirement of physician oversight and a prescription for access to all codeine products, including ECPs. This would be in line with current clinical guidelines recommending that codeine use should only be used with physician oversight.14,16

While there are those benefiting from ECP use without any adverse consequence, there are alternatives on the market that are available without a prescription, with equally demonstrated clinical efficacy and superior safety profiles.6,7 Switching analgesics would be a simple transition for retail pharmacies to undertake as the alternatives are similar in cost; this would not burden the public healthcare system nor contribute to suboptimal pain management.

The onus is currently on the pharmacist to refuse sale of ECPs if misuse is suspected. Pharmacy regulation has been the concentration of policymakers,\(^\text{17}\) though it is unrealistic to expect pharmacists to limit sales. There are three major limitations that affect unchecked ECP release:

- Business interests to sell more product.
- Insufficient human resource allotment for interviewing patients in busy pharmacies.\(^\text{18}\)
- Retail pharmacists are not positioned to recognize nor assess opiate abuse and addiction.

Patients are furthermore easily able to bypass the pharmacist with pre-rehearsed scripts or they may resort to aggression or intimidation even if a pharmacist is vigilant in their assessment.\(^\text{17}\) Not surprisingly, as proven by investigative journalism, abusers are still able to acquire ECPs.\(^\text{2}\)

In addition to codeine risks, acetaminophen, the most common additional ingredient in ECPs, is the leading cause of acute liver failure in Canada.\(^\text{19}\) Those that abuse these ECPs do so despite risk and negative consequence\(^\text{20}\) and are at risk for costly hospital stays. For every case of acetaminophen induced liver failure prevented, the public health budget stands to save $2,123.\(^\text{21}\) According to a recent Health Canada safety review, acetaminophen-codeine combination products are often directly responsible for acetaminophen overdoses and acute liver failure.\(^\text{22}\) In addition, many experts have called for a lower daily dose limit of 2600 mg of acetaminophen, a dose easily surpassed in ECP abuse. With such risks with acetaminophen, it surely should not be combined with a drug with such abuse potential like codeine and made available without a prescription.

Media scrutiny of opioid abuse is increasing in frequency and the public is looking to their government to take strategic action. In response, the Federal Minister of Health, the Honourable Jane Philpott, spoke at the 2nd Charting the Future of Drug Policy in Canada Conference in June 2016. She has explicitly endeavoured to delist non-prescription codeine from legislation.\(^\text{23}\)

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Conclusion

With prescribing regulation of opiates becoming more strict in Alberta and British Columbia, non-prescription codeine deserves similar attention. Removal of section 36 from the Narcotic Control Regulations will address Canada’s battle with opioid misuse and realize Health Canada’s mandate to protect the Canadian public. This will represent a progressive approach to protecting the Canadian public from the risks of opioids. We believe that amending the Narcotic Control Regulations is the best way to solve the problem by setting a national standard for all codeine containing products.

Amendment of the Narcotic Control Regulations will ensure that a physician is consulted before release of any codeine preparation and pharmacies will be relied upon to transition ECP users to equally efficacious, safer, over-the-counter alternatives. This can be achieved without sacrificing care and public healthcare budgets will stand to benefit from fewer social and hospital costs associated with misuse and addiction.
Appendix 1 - Legislation for Removal

CONTROLLED DRUGS AND SUBSTANCES ACT
Narcotic Control Regulations C.R.C., c. 1041

36 (1) Subject to subsection (2), a pharmacist may, without a prescription, sell or provide 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.”

(2) 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.

SOR/78-154, s. 5; SOR/85-588, s. 13; SOR/2004-237, s. 16; SOR/2012-230, s. 21.