

## Submission

Consultation: Proposed amendments to the Poisons Standard being referred to the June 2018 meetings of the ACCS, ACMS and Joint ACCS/ACMS

May 2018

## Background

Codeine is an opioid. Opioids are depressant drugs, which means they slow the messages travelling between the brain and the body.

Codeine is used to provide relief from a number of conditions, including:

- Mild to moderate pain
- Severe pain
- Dry irritating cough
- Diarrhoea
- Cold and flu (when combined with antihistamines and decongestants)

Codeine is usually swallowed and comes in different forms, including tablets, capsules, suppositories and liquids.

Previously, preparations containing 12 mg or less of codeine were available as Schedule 2 or Schedule 3, but from 1st February 2018, these were up-scheduled to Prescription Only (S4).

## Proposal

### Current Scheduling

Codeine is currently in Schedules 4 and 8 and Appendix K of the Poisons Standard.

### Proposed Scheduling

A request has been made to amend the Schedule 4 and 8 entries for codeine to:

- Up-schedule codeine from Schedule 4 to Schedule 8 when in divided preparations containing more than 12 mg of codeine per dosage unit;
- Up-schedule codeine from Schedule 4 to Schedule 8 when in undivided preparations containing more than 0.25 per cent of codeine; and
- Amend both Schedule 4 and 8 entries for codeine to reflect these changes.

### **Schedule 4 - Amend Entry**

CODEINE when compounded with one or more other therapeutically active substances:

- a. in divided preparations containing ~~30~~12 mg or less of codeine per dosage unit; or
- b. in undivided preparations containing ~~4~~0.25 per cent or less of codeine.

### **Schedule 8 - Amend Entry**

CODEINE **alone or when compounded with one or more other therapeutically active substances:**

- a. in divided preparations containing more than 12 mg of codeine per dosage unit; or

b. in undivided preparations containing more than 0.25 per cent of codeine

**except** when included in Schedule 4.

### **CONSEQUENCES WITH UP-SCHEDULING**

There is a wide variety of unintended consequences that will come with the up-scheduling of products containing more than 12 mg of codeine.

#### **Difficulty Storing S8 Products**

There are strict requirements that must be adhered to when storing S8 products. These conditions mean that for the bulk of sponsors, new infrastructure must be put in place in order for them to continue to supply products containing more than 12 mg of codeine.

Based on our current supply levels, we would need to spend in excess of \$1.5 million dollars expanding our S8 storage receptacle, in order to accommodate the additional codeine stock. Given that the current price to pharmacy of paracetamol/codeine 500 mg/30 mg is \$1.35 per pack of 20 tablets, the additional cost would have a significant impact on our cost of goods and would result in the product being no longer sustainable to supply, hence we would have no option but to discontinue the product.

Alternatively, if we did not expand our S8 storage facilities, we would only be able to hold one fifth of our current stock supply, which in turn would result in continuous out of stocks of the product.

We have already seen a similar situation occur when alprazolam was up-scheduled to S8 at the beginning of 2014. Currently there are only two brands of alprazolam available, compared to six when it was a S4, with the market dropping from over 900,000 packs per year to under 400,000.

There has not been a decline in the number of medical conditions requiring treatment with alprazolam, it could even be argued that there has been a significant rise in the number of people suffering from anxiety-related conditions. Rather, doctors are seeking alternative medicines in the "Prescription Only" schedule to meet their patients' needs.

#### **Alternative Medicines**

If the up-scheduling of products containing more than 12 mg of codeine were to occur, another unintended consequence would be the prescribing of alternative S4 products. We have already seen this trend occur, with a sharp increase in sales of ibuprofen/paracetamol coinciding with the movement of over-the-counter codeine-containing products to S4.

An obvious alternative to paracetamol/codeine 500 mg/30 mg combinations is that of tramadol. However, the tramadol market is approximately 10% of the current paracetamol/codeine market and this rise in prescription would result directly in supply and demand issues, with patients being unable to source readily available S4 medication for pain relief.

### **CONCLUSION / RECOMMENDATIONS**

While we support the need for patient safety, we cannot support the proposed up-scheduling due to the unintended consequences that make the change untenable.

As a result of the unintended consequences, sponsors will discontinue their brands and it will put supply and demand pressure on other S4 pain relief products to cover this burden, causing further medicine shortages.

One of the main contributing factors with the revised scheduling of over-the-counter codeine products was to bring Australia in-line with the rest of the world when it comes to the classification of this molecule. With all codeine containing products in Australia currently sitting as Prescription Only, we have in fact reached that goal. However, no other country classifies codeine as a “Controlled Substance (S8)” or an equivalent of this in the respective overseas countries. By further restricting products containing more than 12 mg of codeine to S8, we are now taking ourselves out of alignment with the rest of world.

1. Do not change the current scheduling of codeine
2. Alternatively, change the proposal of the wording to keep it consistent with the current scheduling terminology:

#### **Schedule 4 - Amend Entry**

CODEINE when compounded with one or more other therapeutically active substances:

- a. in divided preparations containing **less than 30** mg or less of codeine per dosage unit;  
or
- b. in undivided preparations containing **less than 1** per cent or less of codeine.

#### **Schedule 8 - Amend Entry**

CODEINE **alone or when compounded with one or more other therapeutically active substances:**

- a. in divided preparations containing **more than 30 mg of codeine per dosage unit; or**
- b. in undivided preparations containing **more than 1 per cent of codeine**  
**except** when included in Schedule 4.