Medicines containing codeine

Implications for hospitals

What is changing?

In December 2016, the Therapeutic Goods Administration (TGA) announced the final decision that over-the-counter medicines containing low-dose codeine will become prescription only products from 1 February 2018. Codeine containing products affected include cold and flu remedies and combination analgesics, such as *Panadeine*, *Nurofen Plus* and *Mersyndol,* as well as generic brands.

Why are these changes occurring?

Research has repeatedly shown that the low dose of codeine available over-the-counter provides no more pain relief than products with paracetamol or ibuprofen alone. So, there is little need for low-dose codeine, especially when there are safer and more effective options available to help manage cold and flu symptoms and pain, both pharmacological and non-pharmacological.

In addition, because codeine is an opioid medicine in the same family as morphine, it can be highly addictive and long term regular use can lead to tolerance, dependence, toxicity and in high doses, death.

Research conducted by the National Drug and Alcohol Research Centre at the University of New South Wales* indicated that the rate of codeine related deaths in Australia more than doubled between 2000 and 2009, driven primarily by an increase in accidental overdoses.

Much of the toxicity from excessive use of codeine related products comes from the co-formulated ingredients, particularly paracetamol and ibuprofen. Overdose of paracetamol can result in liver damage and long term or high dose ibuprofen use can lead to internal bleeding, kidney failure, elevated blood pressure, heart attack and stroke. Evidence shows that long term use of opioids can make chronic pain worse by causing hyperalgesia.

What does this mean for hospitals?

In preparing for the 1 February 2018 change, all hospitals could take the opportunity to conduct a Drug Utilisation Review and identify whether S3 aspirin/codeine 300/8mg and paracetamol/codeine 500/15mg are being used appropriately, given the limited additional benefit of these products as compared to the analgesic efficacy of aspirin or paracetamol.

The TGA commissioned literature review is a useful resource to inform a Drug Utilisation Review – see https://www.tga.gov.au/alert/review-efficacy-and-safety-over-counter-codeine-combination-medicines.

Labelling

In terms of the labelling of stock, section 11 of the Health (Drugs and Poisons) Regulation 1996 (HDPR) requires that part two of the Poisons Standard must be complied with. Part two includes a provision to grant an exemption to the labelling requirements. With regards to the rescheduling of codeine, the TGA has advised the following:

- Remaining stock on hand with Schedule 2 (S2) or 3 (S3) labelling can still be dispensed until 31 October 2018 providing:
    - There is a valid prescription (for outpatient or discharge) or medication order (for inpatients) for the product.
    - The stock is stored in the hospital pharmacy dispensary.
    - The regulations pertaining to Schedule 4 (S4) medicines are followed.

Practically, for Queensland hospitals, this means:

- If low-dose codeine containing analgesics are used in ward areas, the exemption from the S4 labelling is allowed for up to nine months or when the stock expires, whichever is sooner.
- No quantity of S4 low-dose codeine containing analgesics is to be supplied to a patient without a dispensed medicine label, whether or not the manufacturer's label says S3 or S4.
- For Emergency Department (ED) and after hours stocks intended to be supplied by a medical officer to a patient, this residual S3 labelled stock should be pre-prepared with a dispensed medicine label to prevent unlabelled stock being supplied to a patient.
- A dispensed medicine label, in addition to providing instructions for use, makes it clear that the patient is in lawful possession of the S4 medicine, and is therefore not committing an offence under the HDPR.

Other implications for supply

There are a number of issues that hospitals should consider in the lead up to the change from 1 February 2018. These include:

1. Any codeine-containing combination analgesic that is supplied by an authorised person MUST have a dispensed medicine label that complies with *section 198* of the HDPR including the No. 1 red warning label for drowsiness.
2. Except in specific circumstances, registered nurses or enrolled nurses cannot supply any scheduled medicines to patients e.g. in the Emergency Department after hours or to patients on discharge.
3. These items should be removed from any nurse-initiated medicines list – registered nurses' right to administer a medicine without a written instruction is only for S2 and S3 medicines.
4. The storage arrangements in *section 211* of the HDPR apply, whether the medicine is in the pharmacy, an imprest or ED after hours medicines cupboard as per any S4 medicines. The hospital may wish to review storage requirements if patterns of use suggest pilfering or diversion.
5. How these S4 codeine containing analgesics are distributed around the hospital and the circumstances in which they are dispensed or supplied by a medical officer in the Emergency Department should be reviewed to ensure compliance with the HDPR and to deter theft and diversion.
6. Please note that codeine as an S4 is also a restricted drug of dependency so *sections 212-213* of the HDPR also apply.
7. Patient's own supplies of codeine-containing analgesics even if labelled as S3 need to be treated as an S4 after 1 February 2018 in terms of medication orders and storage.

Where can I get more information?

- The TGA Codeine Hub: https://www.tga.gov.au/codeine-info-hub
- NPS Medicinewise: https://www.nps.org.au/
- Scriptwise: http://www.scriptwise.org.au/codeine
- Queensland Legislation: https://www.legislation.qld.gov.au/browse/inforce

*Roxburgh, A., et. al. (2015). Trends and characteristics of accidental and intentional codeine overdose deaths in Australia, Med J Aust; 203 (7): 299.