Up-scheduling of over-the-counter codeine-containing medicines

**Summary** To inform staff in public health facilities of the up-scheduling of over-the-counter (OTC) low-dose codeine-containing medicines to Schedule 4 (prescription-only) of the NSW Poisons List from 1 February 2018.

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**Distributed to** Ministry of Health, Public Health System

**Audience** Clinical, Nursing, Emergency departments, Pharmacy, Drugs & Therapeutics Committees

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**Secretary, NSW Health**

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
UP-SCHEDULING OF OVER-THE-COUNTER CODEINE-CONTAINING MEDICINES

PURPOSE

To inform staff in public health facilities of the up-scheduling of over-the-counter (OTC) low-dose codeine-containing medicines to Schedule 4 (prescription-only) of the NSW Poisons List from 1 February 2018.

KEY INFORMATION

Codeine-containing OTC medicines are to be up-scheduled from Schedule 2 or 3 to Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons, and consequently of the NSW Poisons List, on 1 February 2018.

The up-scheduling of OTC codeine-containing medicines applies to solid dose units (tablet or capsule) containing up to 12 mg codeine (equivalent to approximately 15 mg codeine phosphate) and liquid dose forms containing up to 0.25% codeine. These medicines (if also containing non-opiate therapeutic substance/s and with a recommended daily dose up to 100mg codeine, and in packs up to 5 days' supply) are currently available without prescription for pain relief and for symptomatic treatment of coughs and colds. Of note, the scheduling of all other codeine-containing medicines remains unchanged (i.e. Schedule 8 or Schedule 4).

Implications for public hospitals:

- Hospital/Local Health District drug formularies should be reviewed to determine if low-dose codeine-containing medicines should be removed in light of the lack of evidence for efficacy greater than non-opioid analgesic medicines, and the risk of harm.

- Low dose codeine-containing medicines must no longer be included in Nurse Initiated Medicines (NIM) lists. However, Medication Standing Orders can be approved by the Drug and Therapeutics Committee (DTC) for specific medicines to allow Nurse/Midwife initiation of treatment if appropriate, noting that this requires an authorised prescriber to countersign the record of the administration within 24 hours.

- Electronic Medicines Management systems (eMM) must be reviewed to reflect changes to Nurse Initiated Medicines lists and hospital drug formularies.

- Availability of low-dose codeine-containing medicines in clinical areas (e.g. on ward imprest and any pre-packs kept in Emergency Departments) should be reviewed in light of removal from NIM lists and drug formulary changes. They should be retained only if considered to be clinically necessary as first-line pain treatment, in light of the evidence of lack of efficacy and risk of harms.

- Staff access to low-dose codeine-containing medicines must be vigilantly maintained in the Pharmacy and clinical areas to minimise the risk of misappropriation. This includes removal of all low-dose codeine-containing medicines from First Aid kits.

- Although Schedule 4 codeine-containing medicines are not currently in Appendix D of the Poisons and Therapeutic Goods Regulation (prescribed restricted substances), some facilities/LHDs have local policies requiring storage, recording and accountability for them, equivalent to S4D requirements. Such policies, where present, should also
apply to low-dose codeine medicines if a facility decides to keep them or if patients bring their own into hospital.

- Protocols for pain management on discharge should be reviewed to ensure they describe appropriate analgesic selection and the consideration of access to ongoing analgesia as required. There should be an opioid cessation plan for all patients discharged on oral opioids for acute pain such as after surgery and this should be communicated in writing to the patient and his/her general practitioner (GP).

- Patients should be informed of changes to the scheduling of low-dose codeine medicines if relevant, and referred for information to the consumer information on the TGA Codeine Hub [https://www.tga.gov.au/codeine-info-hub](https://www.tga.gov.au/codeine-info-hub) or provided a copy of relevant leaflet/s.

- Patients who have been self-managing chronic pain with OTC codeine-containing medicines, or those with a substance use disorder involving codeine (e.g. those displaying signs or symptoms such as tolerance, dependence, withdrawal), may present to hospital Emergency Departments, outpatient services, pain clinics or addiction services. Requests for doses or prescriptions for opioid medicines, including codeine-containing medicines, may increase. Facilities should have a documented consistent approach to dealing with such requests. Chronic or acute pain management protocols should be implemented and patient referral to pain clinics and addiction services considered as required. For further information refer to the ACI pain management website at [www.aci.health.nsw.gov.au/chronic-pain](http://www.aci.health.nsw.gov.au/chronic-pain).

**BACKGROUND - Why are these medicines being up-scheduled?**

1. Codeine (methyl morphine), an opioid drug commonly used for the relief of mild to moderate pain, is itself a weak analgesic which must be metabolised to its active metabolite, morphine, to have a therapeutic effect. There is large variability in individual responses to codeine – from poor metabolisers, who experience little therapeutic effect, to ultrarapid metabolisers, who have faster conversion of codeine to morphine, and therefore a greater risk of toxicity.

2. Current OTC codeine-containing medicines offer little or no additional pain relief when compared to paracetamol or ibuprofen alone. There is also limited good quality evidence of efficacy for the inclusion of codeine in cough and cold medicines as a cough suppressant, and significant health risks have been reported particularly in children younger than 6 years.

3. Although common adverse effects of codeine, including nausea, vomiting, constipation and drowsiness, are more likely with higher or repeated doses, medication overuse headaches, drowsiness and an increased risk of falls and motor vehicle accidents are reported even at recommended doses. Codeine should be used with caution in children, breastfeeding women and the elderly.

4. There is substantial evidence of harm, including tolerance, dependence, addiction, poisoning and, in high doses, even death, from the use, abuse and misuse of low-dose codeine-containing medicines. Opioid withdrawal symptoms upon cessation can perpetuate the cycle of misuse and dependency.

5. Adverse effects of the long term or excessive use of combination codeine medicines containing paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) have resulted in a rise in morbidity and mortality associated with liver damage, gastrointestinal
perforations and respiratory depression. There are numerous case reports of serious adverse effects and deaths from combination codeine medicines, particularly related to paracetamol-induced hepatotoxicity and NSAID-induced gastrointestinal ulceration.

A summary of the rationale and evidence behind the up-scheduling of low-dose codeine medicines can be found on the Therapeutic Goods Administration (TGA) website: Regulation Impact Statement: Codeine re-scheduling.

Further information on the health risks of low-dose codeine medicines is on the TGA website:

- George report: Review of the efficacy and safety of over-the-counter codeine containing analgesics for pain and codeine based antitussives
- Safety review: Codeine use in children and ultra-rapid metabolisers