

Codeine: Up-scheduling of codeine-containing medicines to Schedule 4 Prescription Only

POSITION STATEMENT

Position

The Society of Hospital Pharmacists of Australia (SHPA) supports the Therapeutic Goods Administration (TGA) decision to up-schedule all codeine-containing medicine products in Australia to Schedule 4 Prescription Only. Codeine rescheduling is an important step to support patient safety and the quality use of medicines.

Changes in access to codeine-containing medicines encourage health professionals to focus on underlying pain management issues, assess potential dependency issues in conjunction with patients, and direct patients to relevant healthcare practitioners and services.

Discussion

SHPA supported codeine up-scheduling due to concerns about inappropriate use, as well as lack of evidence demonstrating the efficacy of low-dose codeine. SHPA is committed to facilitating the safe and effective use of medicines.

Codeine preparations are often used in combination with paracetamol and ibuprofen.

- Schedule 2 (Pharmacy Medicine) preparations include codeine in combination with cold and flu products, including phenylephrine, paracetamol and chlorpheniramine.
- Schedule 3 (Pharmacist Only Medicine) preparations include codeine in combination with paracetamol, ibuprofen or aspirin.

From 1 February 2018, the TGA tightened regulatory control on all codeine-containing preparations previously listed under Schedules 2 (Pharmacy Medicine) and 3 (Pharmacist Only Medicine). This meant they could no longer be purchased at a community pharmacy or supermarket without a prescription. The decision to move these medicines into Schedule 4 (Prescription Only)¹ was based on strong evidence of codeine misuse and dependency in the community, and consensus from many health professionals. Concern about the safety of codeine and its variable effect in patients^{2,3}, has also been documented in [Therapeutic Guidelines: Analgesic](#).

Codeine is an opioid analgesic that can cause dependency, tolerance and in high doses, death⁴. Research shows that low-dose codeine preparations containing less than 30mg per dose, offer questionable benefits when compared to analgesics such as paracetamol and ibuprofen, but still cause adverse effects such as drowsiness, nausea, rebound headaches⁵ and constipation. It has been reported that prolonged use of codeine leads to liver damage.

Opioid analgesic	Pain reliever belonging to the family of medicines called opioids.
Dependency	The body has become used to the effects of the medicines and may experience withdrawal if the medicine is taken away.
Tolerance	The effect of the medicine decreases with repeated use.

SHPA members frequently assist in the management of cases of codeine misuse detected in emergency departments and during hospital admissions. Codeine misuse has been implicated in many opioid drug-related deaths in Australia. In the five-year period between 2007 and 2011, there were 1,857 deaths related to codeine misuse, considerably more than the 1,127 deaths attributed to illicit heroin use⁶.

The costs associated with hospitalisations related to codeine misuse are a significant burden on the Australian health

system. A five-year observational study conducted at a tertiary teaching Australian public hospital found 99 admissions related to codeine misuse resulting in an estimated cost to the local healthcare system of \$1,008,082, and an average cost of \$10,183 per patient admitted into a hospital⁷.

Conclusion

Making codeine available only through a doctor's prescription provides an opportunity for hospital pharmacists to help patients understand the risks of codeine and broader opioid use, identify pain management issues and establish treatment plans. The inpatient setting is ideally suited for pharmacists to begin conversations about best practice in managing and treating pain. The discharge setting is suited to counselling and education and establishing treatment plans post-discharge with appropriate follow-up and review. This can be achieved by:

- Discussing alternative options to manage and treat acute and/or chronic pain with patients and treating teams
- Addressing issues of dependency in an inpatient setting and referring to relevant services post-discharge if necessary
- Establishing a pain management treatment plan and communicating this to GPs, community pharmacists, and carers
- Carefully considering the initiation of any strong pain relievers such as opioids, especially with patients who have never been treated with these before.
- Ensuring codeine and other opioids are only used for patients with acute pain when medically assessed as required, and for the shortest duration possible.

Recommendations

The change in the availability of codeine-containing medicines offers the chance to re evaluate current practice around how patients treat pain issues and address the needs of patients in holistic and effective ways.

SHPA recommends:

- Hospital pharmacies review the inclusion of low-dose codeine products on hospital formularies, including limiting supply based on patients' need rather than product pack size.
- Hospital pharmacists should prioritise education about appropriate analgesic use and pain management to consumers and health professionals.

- As part of a multidisciplinary team, hospital pharmacists should establish pain management and/or opioid de-escalation plans for all patients discharging with opioid medicines, and communicate these with the patients' GP, community pharmacy, and carer.
- In partnership with medical practitioners, hospital pharmacists should support the review of protocols for pain management to ensure they include appropriate ongoing analgesic selection. In cases of chronic pain this also provides an opportunity to ensure access to multidisciplinary pain management programs.
- The expansion of opioid stewardship programs clearly defining when, how, why and for how long strong pain relievers such as opioids should be prescribed, and by whom should be given priority in the hospital setting.

VERSION: 1
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