



National Prescribing Service Limited

NPS Position Statement December 2009

Quality use of over-the-counter codeine

Background

Codeine is widely used in combination products, mostly as an analgesic. It is a weak opioid which achieves its analgesic action through conversion to morphine in the liver. Only 5-15% of a dose of codeine is metabolised to morphine. Approximately 6-10% of Caucasians and 1-2% of Asians lack the enzyme which converts codeine to morphine and are unlikely to achieve any pain relief with codeine.¹

Combination products

In Australia, codeine products have been available over-the-counter (OTC) for the treatment of mild to moderate pain or cough suppression. OTC codeine products are only available in combinations, usually with decongestants and/or analgesics. Until now, these products have been included in Schedule 2 (Pharmacy Only medicines) and Schedule 3 (Pharmacist Only medicines) depending on the codeine strength, the pack size and State jurisdiction. Higher strength preparations are prescription only medicines.

Misuse

There is concern that combination analgesics containing codeine are being misused as an adjunct to drugs of abuse or by people who become dependant on chronic pain medication. There have been particular concerns regarding use of large volumes of combination products containing ibuprofen and codeine with reports of perforated gastric ulcers, severe hypokalaemia secondary to renal tubular acidosis and renal failure with long term use.^{2,3} This combination may be more vulnerable to abuse because it has relatively high codeine content and lacks the fatal toxicity in overdose associated with paracetamol.

Scheduling changes

As of May 2010, combination products for analgesic, but not cough and cold, preparations will be rescheduled to Schedule 3 (Pharmacist Only) with the following restrictions:

- Pack size limited to 5 days supply
- Maximum dosage unit of 12 mg codeine (15.4 mg codeine phosphate).
- Larger pack sizes and higher strengths of codeine will be prescription only medicines.

Quality use of medicines issues

Given reports of escalating Emergency Department presentations for gastric ulcer perforation secondary to excessive ibuprofen-codeine use there is a need for action in this area. The evidence for misuse of codeine combination products is compelling yet there is a lack of data that fully describes the extent and nature of the problem.

The regulator's response has been to limit access to codeine combinations by rescheduling the products which will require a pharmacist to be involved in all sales, product to be stored under the supervision of the pharmacist and pack sizes to be reduced. This paper considers how quality use of codeine-containing preparations can be best achieved, taking account of these scheduling changes.

Non-drug options

Pharmacists, allied health professional, nurses and doctors are all involved in recommending OTC analgesics. All are responsible for ensuring that appropriate non-drug options are explored with the patient, either instead of analgesics or as an adjunct to medication.

Effectiveness

All professional groups should be aware of and support evidence-based guidelines for pain management. Regular paracetamol is still recommended as initial therapy for most forms of chronic pain with non-steroidal anti-inflammatory drugs as second-line alternatives if paracetamol alone is not adequate. Codeine-containing analgesics have a limited role in chronic pain management.

The rescheduled analgesics will contain up to 12 mg codeine per tablet, for a total dose of 24mg. Therapeutic Guidelines recommends that 25-30 mg codeine is required for effective pain relief.⁴ And up to 10% of patients will have no response at all due to their inability to metabolise codeine to morphine.

The NPS position is that codeine-containing analgesics should be recommended by health professionals only when they are truly indicated as identified in national guidelines and following assessment of the individual patient. If treatment is not successful then alternative strategies should be considered, rather than escalating the dose.

Safety

Overuse and misuse of codeine-containing products occurs both intentionally and unintentionally. Opioid use can lead to dependence, tolerance and escalating doses in patients who are using analgesia for reasonable indications if their pain is not well managed. Others may use codeine products as adjuncts to illicit drugs, or as a cheaper or more accessible source of narcotic.

Safety issues arise because the co-analgesics in these products, paracetamol, aspirin and ibuprofen, are all toxic in high doses. High doses of combination products can result in liver toxicity and death in the case of paracetamol or gastric ulcer perforation for ibuprofen and aspirin.

In addition there are the well understood adverse effects of codeine such as constipation which should be considered when prescribing any combination product.

NPS supports the scheduling changes which increase the checks and balances for provision of codeine-containing products both through the pack size and face-to-face interaction with the pharmacist. These measures, however, are unlikely to adequately address all safety concerns. Pharmacists are well placed to encourage safe use of analgesics but they will require both skills and systems to support them.

Access

Changes to pack sizes will reduce OTC accessibility of codeine-containing analgesics and require that some people shift to prescription medicines supplies. This may disadvantage a very small group of users but it is likely that some of this use is not consistent with guidelines and that the patient would benefit from a review of their analgesic use. Ideally health professionals, particularly pharmacists will use the change in scheduling to identify patients requiring more support to use analgesics safely and effectively.

NPS believes it will be important to monitor the overall costs to patients and the government of the regulatory change so that its financial impact can be gauged and unintended consequences identified.

Improving quality use of combination analgesics containing codeine

The regulatory changes due to take effect in May 2010 are supportive of a safer system but they are unlikely to be enough. Quality use of medicines would be enhanced by implementation of the following measures.

Understanding the problem

It would be useful to have better data on OTC codeine use with respect to the following questions:

- Is it primarily OTC analgesics which are misused rather than cough and cold preparations containing codeine? Does this change with the change in scheduling?
- How large a problem is misuse and drug seeking behaviour?
- What proportion of misuse is unintentional and/or unrecognised by the patient?
- What conditions are OTC analgesics containing codeine being used for? And for how long? And in what quantities?

Such detailed data would permit better targeting of education programs and assist policy makers to assess both the current rescheduling proposal and other options, including electronic notification systems.

NPS does not suggest that all action should await the availability of better data. Rather, we support immediate action with data collection mechanisms being developed to support future work and evaluate current activity.

Education and standards

All health professionals who are involved in recommending OTC analgesics should be aware of evidence-based guidelines and tailor therapy for the individual patient, ensuring they and the patient share similar expectations in terms of possible harms and benefits. This requires not only knowledge about guidelines but skills such as therapeutic assessment and motivational interviewing.

In the case of obvious misuse and drug seeking behaviour, pharmacists need skills and systems to deal with difficult, aggressive or hostile behaviour in a safe environment. Professional bodies and NPS have a role in providing access to knowledge resources, skills training and in helping to develop safer practice models for dealing with difficult customers.

The Pharmaceutical Society of Australia's (PSA) Standards for provision of Pharmacist Only medicines

and the Pharmacy Guild's Quality Care Pharmacy Program Standards provide excellent best-practice guides to support prescribing of OTC codeine. It will be essential that implementation of the standards is uniform and consistent if rescheduling is to achieve the gains envisaged. Professional bodies have an important role to play in ensuring universal uptake of the standards.

Professional organisations have indicated an intention to provide education programs for members.

Community awareness

As consumers commonly self-manage their pain, consumer demand is an important driver of OTC analgesic use. For this reason it is essential that the community becomes more aware of safe and appropriate use of all analgesics, including those containing codeine. An important first step is for people to be aware of the active ingredients in OTC products. NPS will undertake a program of work over the next two years in collaboration with our member organisations, including Consumers Health Forum and PSA.

NPS recommends that this should be supplemented by government and other organisations to include community engagements, awareness campaigns and mass audience strategies to reach the community at large.

Testing new options

There have been proposals for electronic notification systems to be used as a means of monitoring and preventing inappropriate use of codeine-containing analgesics. Different strategies are obviously needed for drug seeking behaviour compared to unintentional misuse and notification systems must be adaptable for different patient groups and accompanied by adequate up-skilling of pharmacists. NPS believe it would be useful to test notification systems, preferably in a randomised controlled trial, undertaken by a party without competing interests.

Draft National Pain Strategy

A draft National Pain Strategy was launched in October 2009 for consultation. And the final Strategy is expected mid-2010. The purpose of the Strategy is to minimise the burden of pain on individuals, families and the community. It has four goals:

- People in pain as a national health priority
- Knowledgeable, empowered and supported consumers
- Access to skilled professionals and best-practice evidence-based care
- Access to interdisciplinary care at all levels.

NPS supports incorporation of the Strategy's principles into initiatives to improve use of OTC codeine.

Conclusions

Quality use of codeine-containing analgesics will be supported by the scheduling changes that take effect in May 2010. In order for their full benefit to be achieved and for safer and more effective use of analgesics NPS recommends that additional work will be essential, including:

- activity to support an appropriately educated and skilled workforce
- systems that support appropriate prescribing of OTC analgesics
- activity to improve consumer awareness of the risk, benefits and appropriate use of OTC analgesics
- trials of new policy options and systems
- availability of data to understand the problem, evaluate what we are doing now and design interventions for the future.

References

1. Rossi S, ed. Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd, 2008
2. Dutch MJ. Nurofen Plus misuse: an emerging cause of perforated gastric ulcer. Medical Journal of Australia 2008; 188: 56-57
3. Dyer, BT et al. Hypokalaemia in ibuprofen and codeine phosphate abuse. International Journal of Clinical Practice 2004; 58: 1061-1062
4. Analgesic Writing Group. Therapeutic Guidelines: Analgesic. Version 5. Updated September 2007 [eTG complete CD-ROM]. Melbourne: Therapeutic Guidelines Ltd, 2007

The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence. Any treatment decisions based on this information should be made in the context of the clinical circumstances of each patient.