FACULTY OF PAIN MEDICINE
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Advancing pain medicine:
Improving patient care

DEAN
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Adj Prof Tim Greenaway
Chair, National Coordinated Codeine Implementation Working Group
Therapeutic Goods Administration
Department of Health
Canberra ACT

Tim.Greenaway@health.gov.au

Dear Dr Greenaway

Re: Rescheduling of codeine from S3 to S4

The Faculty of Pain Medicine (FPM) of the Australian and New Zealand College of Anaesthetists (ANZCA) is pleased to re-assert strongly its support for the rescheduling of codeine from S3 to S4.

FPM is the body responsible for the education, training and continuing professional development of specialist pain medicine physicians in Australia. The Faculty promotes appropriate prescribing for pain relief through its professional documents[1]. Furthermore, safety and high quality patient care in anaesthesia, perioperative medicine and pain medicine, is part of ANZCA's mission.

In submissions in June 2015, October 2015 and April 2016, FPM noted that the proposed rescheduling of codeine would not only address major clinical and public health issues but also align Australia with other jurisdictions such as United States, Sweden and Germany where all codeine-containing preparation require prescription by a medical practitioner for sound reasons.

FPM would like to reiterate the three key reasons for this stance.

1. **The addition of low-dose codeine to non-opioid analgesics provides little additional analgesic benefit, while at the same time there are more effective alternatives for the treatment of "acute" pain.**

The evidence for this is best summarized in the internationally endorsed publication, *Acute Pain*

[1] http://www.fpm.anzca.edu.au/resources/professional-documents

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Management: Scientific Evidence[2], from studies of post-operative pain as a model for the pain of acute injury:

- Oral codeine in a single dose of 60 mg is *not* an effective analgesic agent after a variety of operations (NNT[3] 12); this effect was even smaller in the subgroup after dental surgery (NNT 21).
- When combined with oral paracetamol, codeine 60mg was associated with NNTs of 2.2 - 3.9, while codeine 30mg was associated with NNT of 6.9. The duration of analgesia was extended by only 1 hour compared with paracetamol alone.
- There are no data on combinations of oral paracetamol with codeine doses less than 30 mg.
- Current evidence shows improved analgesia with codeine 60 mg and ibuprofen 400 mg compared with ibuprofen alone, but there are minimal data for lower doses.
- Furthermore, a number of studies have identified that combinations of ibuprofen plus paracetamol provide superior analgesic efficacy to OTC codeine combination analgesics.

2. Dependence on OTC codeine-containing analgesics is a significant concern and can cause serious, sometimes life-threatening adverse effects due to the combination with paracetamol or NSAIDs.

As has been argued previously, dependence on and abuse of codeine-containing combination preparations available on S3 leads to significant organ toxicity due to the consumption of excessive doses of the non-opioids in these combinations: paracetamol (liver toxicity) and ibuprofen (gastrointestinal and renal, if not also cardiovascular toxicity).

This is especially a problem when these drugs are used, often in excess, for the management of chronic pain, which is often part of a set of more complex clinical situations than acute pain. The management of chronic pain requires medical practitioner input for comprehensive assessment and advice on non-drug treatments and on appropriate use of medicines, rather than long term self-treatment with codeine-containing analgesics.

3. There is significant harm from the easy and widespread availability of OTC codeine-containing medicines.

As has been well documented, dependence on opioid analgesics is a significant health and public health problem in Australia, as in other comparable developed societies. Codeine under Schedule 3 contributes to this problem, by providing completely unmonitored access to an opioid, which although a weak analgesic, is a prodrug to morphine which can create dependence. National and international media have focused attention on the significant and damaging impacts of codeine dependence on the community.

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[2] Schug SA, Palmer GM, Scott DA, Halliwell R, Trinca J. Acute Pain Management: Scientific Evidence. 4E, Melbourne: ANZCA & FPM, 2015.

[3] NNT = number of patients needed to be treated for 1 patient to gain a 50% reduction in pain scores

In summary, FPM and ANZCA maintain that the proposed restriction of access to codeine-containing analgesics is in the best clinical and public health interests of the Australian community.

For further information, contact Helen Morris, FPM General Manager via email hmorris@anzca.edu.au or telephone +61 3 8517 5307.

Yours sincerely

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