



29 January 2016

Department of Health
Therapeutic Goods Administration
Advisory Committee on Medicines Scheduling

Email: medicines.scheduling@tga.gov.au

To whom it may concern,

The RACGP thanks the Advisory Committee on Medicines Scheduling (ACMS) of the Therapeutic Goods Administration (TGA) for the opportunity to provide comment on the proposed amendments to the Poisons Standard (Codeine). These include:

Schedule 2 (cough and cold medicine preparations):

- a. Proposal to amend the Schedule 2 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR
- b. Proposal to up-schedule the Schedule 2 entry to Schedule 3 and reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR
- c. Retain the interim decision to up-schedule to Schedule 4.

Schedule 3 (including, but not limited to codeine containing analgesics):

- a. Proposal to amend the Schedule 3 entry to reduce the pack size to not more than 3 days' supply and include a label warning that codeine can cause addiction; OR
- b. Retain the interim decision to up-schedule to Schedule 4.

The Royal Australian College of General Practitioners (RACGP) is the specialty medical college for general practice in Australia. We represent over 30,000 members working in or towards a career in general practice.

The RACGP supports the decision to retain the interim decision to up-schedule to Schedule 4. We believe that on balance, the evidence suggests rescheduling is a necessary step to improve patient safety and reduce harm. There is increasing evidence of serious harms from over the counter (OTC) codeine combination analgesics. This harm has not been reduced by restricting medicines to pharmacy only.

The RACGP supports the availability of safe and effective medications for consumers to self-manage minor pains. However, the evidence is clear that the 8mg and 15mg doses of codeine (in the OTC codeine combination analgesics) are "sub-therapeutic" i.e. they offer no benefit above the Panadol/Nurofen combination, to which they are added. Indeed, combinations of ibuprofen plus paracetamol provide superior analgesic efficacy to the OTC codeine combination analgesics and should be readily available and promoted as superior alternatives.



RACGP

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Codeine based OTC medications are “big business” and as a result, there is likely to be significant pressure to resist rescheduling of these medications. We urge the Advisory Committee on Medicines Scheduling to resist these business pressures. The case for rescheduling is clear as the evidence demonstrates ineffective therapeutic effect and a generation of significant harm.

Yours sincerely

Dr Frank R Jones
President