



17 October 2022

Advisory Committee on Medicines Scheduling (ACMS)
Department of Health and Aged Care
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Via email: medicines.scheduling@health.gov.au

Dear Advisory Committee on Medicines Scheduling (ACMS),

Re: Public consultation on proposed amendments to the Poisons Standard (paracetamol)

The Royal Australian College of General Practitioners (RACGP) thanks the Therapeutic Goods Administration (TGA) for the opportunity to provide comment on the proposed amendments to the Poisons Standard (paracetamol).

GPs see many patients with acute or chronic pain. Pain relief that is effective and evidence-based can be an important part of a treatment regimen to ensure patients continue to have a good quality of life. However, the RACGP also advocates for the safe and appropriate use of medicines and ensuring patient safety at all times. The RACGP includes a [pain management](#) unit as part of the 2022 Curriculum, and provides clinical guidelines such as [Prescribing drugs of dependence](#) guideline suite, the [Handbook of Non-Drug Interventions \(HANDI\)](#) and the [Guideline for the management of knee and hip osteoarthritis](#). In the latter guideline, we were unable to recommend either for or against the use of paracetamol for people with knee and/or hip osteoarthritis due to insufficient evidence.

The RACGP provides comment on the following proposed changes to the Poisons Standard (paracetamol):

Option 2: Pack size restrictions

Option 2A: *for general sale preparations, to be reduced to 10 x 500 mg tablets/capsules or 5 individually wrapped sachets (amendment to Schedule 2 entry, paragraphs g) (ii)(A) and (iii)(B))*

The RACGP supports the continued availability of paracetamol in non-pharmacy retail stores. We agree that pack sizes should be reduced in these settings. The potential increase in cost from a reduction in pack size needs to be taken into consideration for patients in lower socioeconomic status groups. This may be an issue for patients who are taking paracetamol on a regular basis, so measures should be in place to ensure affordability.

Option 2B: *for pharmacy only medicines, to be reduced to 32 x 500 mg tablets/capsules or 16 individually wrapped sachets (amendments to Schedule 2 entry, paragraphs f) and g) and Schedule 2 entry, paragraphs c), g) (ii)(A) and (iii)(B)).*

The RACGP supports pack size restrictions on pharmacy only medicines.

Options 3A-B: Restrictions on the purchasing of multiple packs

The RACGP supports similar pack size and pack number restrictions for over-the-counter sales in pharmacies and in other retail outlets. The recommended maximum dose of paracetamol for acute pain is eight tablets in 24 hours. Allowing the purchase of two packs of 10 tablets is reasonable and will reduce the tendency for large stockpiles to be kept in the home.

Option 4: Sale from behind the counter

Description: *Display and self-selection of paracetamol in non-pharmacy outlets to no longer be permitted.*

Limiting sales to 20 tablets (a maximum of two packs of 10) in both pharmacies and other retail outlets is preferable. For retail outlets with self check-out arrangements, sales should be from behind the counter.

Option 5: Age restrictions

Description: *The minimum age of purchase to be restricted to those 18 years and over:*

Option 5A: *in pharmacies (amendment to Schedule 2 entry paragraphs c) and e)), or •*

Option 5B: *in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)).*

Additional information is required to assess the benefits and harms of age restrictions on paracetamol sales. Restricting the purchase of paracetamol for people under 18, would be detrimental for those suffering from acute pain, such as headache, period pain or influenza-like symptoms.

Option 6: Modified release paracetamol restrictions

Description: *All modified release paracetamol is rescheduled from Schedule 3 to Schedule 4, without change to maximum pack size.*

The RACGP supports up-scheduling of modified release paracetamol. For acute pain, normal paracetamol is more appropriate. There is an overuse of modified release paracetamol for conditions for which there is insufficient evidence of benefit, such as osteoarthritis and back pain. Additionally, treating overdose from modified release paracetamol is more difficult than normal paracetamol. This due to the particular pharmacodynamics of modified release paracetamol.

Other comments for consideration

Any proposed changes should be piloted before being introduced Australia-wide, with the impacts of the changes being fully evaluated. This review should include identifying any unintended consequences, such as subsequent increase in demand for non-steroidal anti-inflammatory drugs (such as aspirin and ibuprofen) or medicinal cannabis. These medications have their own potential harms that need to be considered. Careful attention should also be made to the implementation of any changes, with a significant public messaging campaign in order to educate the general public on the changes and the reasons for making them.

Importantly, overdose and suicide prevention require a multi-targeted approach, beyond changes to medication access. This includes further support and funding for GPs to provide and refer for youth mental health care, particularly for at risk populations, including people in the LGBTIQ+ and Aboriginal and Torres Strait Islander communities. This should also include increased numbers of affordable psychologist and psychiatrist services for young people to access.

Further support should also be provided for GPs to undertake chronic pain consultations and medication reviews for patients who are taking pain medications, to ensure these medications are being used safely and to identify opportunities for deprescribing and non-drug interventions.



RACGP
Royal Australian College
of General Practitioners

Healthy Profession.
Healthy Australia.

Thank you again for the opportunity to provide a submission to the Proposed amendments to the Poisons Standard (paracetamol). If you have any questions regarding our submission, please contact Mr Stephan Groombridge, National Manager, e-health and Quality Care at stephan.groombridge@racgp.org.au or 03 8699 0544.

Yours sincerely

Adj Prof Karen Price
President