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AMA Submission on Proposed amendments to the Poisons Standard in relation to paracetamol – ACMS meeting, November 2022

The AMA supports efforts to limit harm from medicines misuse. As stewards of medicine safety, medical practitioners have an important role to play in ensuring medicines are accessed appropriately and used safely.

Finding the right balance between limiting harm from overdose and guaranteeing access for people who need paracetamol will be challenging. There will be no universally agreed upon right answer, and we encourage the TGA to review the settings within three years of the changes to ensure they are appropriate.

The AMA's preferred position is that modified release paracetamol is upscheduled, solid dose paracetamol is only available in blister packs, pack sizes are reduced in retail settings, and pack limits are introduced for non-pharmacy settings. The AMA is open to considering introducing an age restriction for purchasing paracetamol in retail settings. Noting that different States and Territories will have different regulation regarding marketing of unscheduled and scheduled medicines, the AMA also suggests considering minimising the display of bulk paracetamol packaging.

While there are safety risks to paracetamol, it also provides an important therapeutic purpose in Australia. It is important that the risk is not overstated, undermining consumer confidence in the safety of the product. We would consider it an adverse outcome if safe use of paracetamol decreased and potentially unsafe use of alternative analgesics increased.

At the same time, too many Australians are reliant on over-the-counter pain medications to manage chronic pain. An added benefit of limiting access to large quantities of paracetamol and upscheduling modified release paracetamol is that these individuals will be forced to discuss their pain with either a GP or a community pharmacist who can refer the patient to a GP if required. GPs can help manage chronic pain or can refer to additional services if needed. This will ultimately lead to improved health outcomes. The AMA supports continuing prescription availability for quantities of 100 and 300 Immediate Release (IR), and a reasonable quantity of Sustained Release (SR) paracetamol. Ready availability of paracetamol is very important in the management of chronic osteoarthritis pain as it is by far the safest option in most older patients where alternative analgesics can be increasingly risky.

In the AMA's response to the survey of options we have used 'partial support' to indicate that this is a good option, but not our preferred. 'Support' indicates our preferred options.

Options 1A-C: Blister packs

Description

Solid dose paracetamol (tablets/capsules) made available only in blister packs (not loose dose units):

- Option 1A: for general sale preparations only (amendment to Schedule 2 entry, paragraph g); **Partial support**
- Option 1B: for general sale and pharmacy preparations only (amendment to Schedule 2 entry, paragraphs c) and g)); **Partial support**
- Option 1C: for pharmacist only, pharmacy and general sale preparations (amendment to Schedule 3 entry, paragraph b) and Schedule 2 entry, paragraphs c) and g)). **Support**
- Option 1D: for prescription only, pharmacist only, pharmacy and general sale preparations (amendment to Appendix D, Schedule 3 entry, paragraph b), and Schedule 2 entry, paragraphs c) and g)) **Do not support**

Comment

The AMA would like to see solid dose paracetamol restricted to blister packs with some exceptions. There will be people in the community who require other options to access paracetamol for mobility issues. Ideally these individuals would have a regular GP to help manage these issues and could prescribe solid dose paracetamol in containers that are easier to use. Additionally, any changes in packaging should take into consideration the cost impact, environmental impact and access impact for patients.

Options 2A-B: Pack size

Description

Reductions in the maximum paracetamol pack size sold in Australian retailers:

- 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)); **Partial support**
- 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)) **Partial support**

Comment

The AMA supports reducing pack sizes for paracetamol available in retail settings, however we do have concerns that limiting size too much, i.e. 10 tablets per pack, may harm some people who are safely managing their pain with paracetamol, in accordance with a plan developed with

their GP. The AMA is also concerned that overly restricting paracetamol will encourage overuse of NSAIDs which carry more risk and do more harm overall, although they may carry less risk of overdosing.

Furthermore, the AMA agrees that the pack size of 100 is large, even when sold at pharmacies, however, we would support halving the size to 50, rather than 32, as proposed by the Consultation Paper.

Ultimately, the AMA would like to see more feedback from consumers on this proposal.

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

Description

Allowing only one pack to be purchased at a time when purchased in the following retail settings:

- Option 3A: without a prescription in pharmacies (amendment to Schedule 2 entry paragraphs c) and e)), or **Partial support**
- Option 3B: in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)). **Partial support**

Comment

The AMA supports pack limits in retail settings. If the pack size is reduced to 10, the AMA would not support limiting packs to only one in a pharmacy. Pharmacists could play a role in ensuring people seeking more packs have a conversation with the pharmacist and understand the risks. There are many reasons an individual may need extra packs, such as purchasing for family members, ahead of travels or simply recovering from an illness or surgery.

Option 4: Sale from behind the counter

Description

Display and self-selection of paracetamol in non-pharmacy outlets to no longer be permitted. **Do not support**

Comment

Limiting pack size and pack limit in non-pharmacy retail settings should satisfactorily limit harm without implying that paracetamol is as risky as other behind the counter items, such as cigarettes. It is important that the risk is not overstated, undermining consumer confidence in the safety of the product. We would consider it an adverse outcome if safe use of paracetamol decreased and potentially unsafe use of alternative analgesics increased.

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 **Do not support**
- Option 5B: in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)). **Partial support**

Comment

The AMA does not support restricting access to paracetamol in pharmacies. There could however be guidelines which ensure a pharmacist speaks with a person under the age of 18 before purchasing paracetamol to make sure they understand the risks.

The AMA is open to supporting age restrictions in non-pharmacy retail settings, although uncertain about its potential impact. In the AMA view, it will be important that consumer confidence in paracetamol safety is not compromised, while at the same time young vulnerable groups are protected. The Independent Report highlights the lack of evidence for any particular access-based restriction impacting deliberate self-harm related paracetamol overdoses. While teenagers are the most at risk group for overdosing, reducing pack size and limits should significantly limit risk from paracetamol poisoning without removing all access to a sometimes very useful medicine. It is also important to note that because Australia has outdated, anticompetitive pharmacy location rules, there are not always conveniently located pharmacies whereas corner stores, petrol stations and supermarkets are always easy to find and stock paracetamol.

Option 6: Modified release paracetamol

Description

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

Comment

The AMA strongly supports upscheduling modified release paracetamol. This will limit harm, as modified release paracetamol is frequently found in overdoses, while also encouraging patients reliant on modified release paracetamol to manage chronic pain to regularly see their GP.

Contact

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