3 March 2023

Therapeutic Goods Administration
Department of Health and Aged Care

via website portal

ARA SUBMISSION TO THE TGA REGARDING INTERIM DECISION TO AMEND SCHEDULING OF PARACETAMOL

The Australian Retailers Association (ARA) welcomes the opportunity to provide comment to the Therapeutic Goods Administration (TGA) regarding its public consultation on the interim decision to amend the scheduling of paracetamol in the Poisons Standard.

The ARA is the oldest, largest and most diverse national retail body, representing a $400 billion sector that employs 1.3 million Australians – making retail the largest private sector employer in the country. As Australia's peak retail body, representing more than 120,000 retail shop fronts and online stores, the ARA informs, advocates, educates, protects and unifies our independent, national and international retail community.

We represent the full spectrum of Australian retail, from our largest national and international retailers to our small and medium sized members, who make up 95% of our membership. Our members operate in all jurisdictions and across all categories - from food to fashion, hairdressing to hardware, and everything in between.

The ARA's membership also includes pharmacy retailers and general retailers who sell paracetamol. Our submission is informed by consultation with both groups of members.

The ARA understands that the interim decision to amend the Poisons Standard was made following an independent expert report that outlined the risks associated with intentional self-poisoning, as well as public consultation and advice from the Advisory Committee on Medicines Scheduling (ACMS).

We note that the interim decision makes the following proposals:

- reduce the maximum size of packs available for general sale (for example, in supermarkets and convenience stores) from 20 to 16 tablets or capsules, with a requirement for blister packaging.
- reduce the maximum size of packs available in pharmacies without supervision of a pharmacist (Schedule 2 'Pharmacy Only' medicine) from 100 to 32 tablets or capsules, with a requirement for blister packaging.
- make other pack sizes up to 100 tablets or capsules only available under the supervision of a pharmacist (Schedule 3 'Pharmacist Only' medicine).

The ARA supports these proposed changes to the Poisons Standard, noting that the complete elimination of any potential risks associated with intentional self-poisoning is not possible. Our view is that any proposed measures need to be balanced and proportionate to ensure consumers still have appropriate access to necessary medicines for the treatment of pain, while addressing public safety concerns.

We also note that the interim decision includes a proposal to encourage retailers to implement a one-pack purchase limit on the general retail sale of paracetamol. We make the following observations and recommendations with regard to that proposal.

- As other proposed changes will reduce pack sizes that are available for sale through general retail, customers will likely need to make more frequent purchases. This will make the suggested one-pack purchase limit more burdensome, particularly for consumers living in rural areas and for elderly and disabled people who may have limited access to shops.

- The ARA recommends that a voluntary two-pack purchase limit would be a more reasonable and proportionate measure that better balances the risk against accessibility. To support this recommendation, we note that the Independent Expert Report found that overdoses involving less than 25g of paracetamol are easier to treat than higher doses and that the proposed pack size limits for general retail will mean that two packets will equate to 16g of paracetamol.

- We believe an industry guideline would be an appropriate tool to support the implementation of this proposal.

- It is unclear whether the TGA's expectation is that the suggested, voluntary one-pack purchase limit would apply separately to different types of paracetamol, for example children's formulations, or would count all formulations the same. Such an expectation could result in an unintended consequence where a customer would be required to choose between purchasing either the children's formulation or adult, rather than being able to buy both. This would be inconvenient for families where everyone is ill at the same time but could potentially increase the risk of unintentional overdosing of children if parents attempted to use adult paracetamol for children.

- The ARA recommends that a voluntary two-pack purchase limit should count different formulations of paracetamol individually to limit the potential risks associated with using an adult formulation for children.

More broadly, we make the following recommendations.

- While the public has had opportunity to comment on the proposed changes, we believe it is unlikely that most consumers would be aware of this review process and the potential outcomes. We strongly recommend that the TGA work with retailers to deliver a comprehensive consumer education campaign that would include clear information and signage at the point of sale. This would also need to be supported by training resources for retail staff and a broader consumer awareness campaign through social media and traditional engagement channels to support implementation and socialisation of the proposed changes.

- Likewise, retailers and suppliers would need a reasonable period to implement compliance frameworks. The ARA recommends further engagement with retailers, suppliers and manufacturers regarding the appropriate timeline and suggest that early 2025 would potentially be reasonable. We also note that it may be prudent to avoid cold and flu season (which typically corresponds with surges in macro demand for pain relief medication) in terms of implementing changes.

Once submissions have been reviewed and a decision is made, the ARA is open to working with the TGA on developing a guideline for retailers in relation to any implementation of the suggested, voluntary purchase limits for general retail.

We also note that the interim decision includes the suggestion that consumers should be encouraged not to stockpile medicines at home and urge that this proposal will need to be incorporated into the consumer education and awareness campaign that supports any changes to the Poisons Standard.

Thank you again for the opportunity to provide a submission to the TGA. Any queries in relation to this submission can be directed to our policy team at policy@retail.org.au.

Yours sincerely,

Paul Zahra
Chief Executive Officer