

10 October 2022

Medicines Scheduling
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606

Submitted via: [consultation hub](#)

ARA SUBMISSION TO TGA REGARDING CONSULTATION ON PROPOSED AMENDMENTS TO THE POISONS STANDARD (PARACETAMOL)

INTRODUCTION

The Australian Retailers Association (ARA) welcomes the opportunity to comment on potential scheduling amendments to the Poisons Standard in relation to paracetamol which we understand will be considered at the November 2022 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

The ARA is the oldest, largest and most diverse national retail body, representing a \$400 billion sector that employs 1.3 million Australians and is 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 across all categories - from food to fashion, hairdressing to hardware, and everything in between.

The ARA understands that the independent expert report, commissioned by the Therapeutic Goods Administration (TGA) has made recommendations based on the risks associated with intentional paracetamol self-poisoning and that the TGA is seeking comments from the public in relation to its consideration of proposed options for amendments to the Poisons Standard in relation to paracetamol. Our comments and recommendations outlined below reflect our own consultation with retailers within the ARA membership who currently sell paracetamol in various settings, including supermarkets and convenience stores.

PROPORTIONATE MEASURES TO LIMIT RISKS

The ARA believes that the Poisons Standard should be amended to address the risks associated with intentional self-poisoning and we note that the risk has been found to be higher with teenage girls. The policy approach should be proportionate to the risks, noting that elimination of risk is not possible but that appropriate measures, implemented as part of a holistic policy can be effective in decreasing risks and preventing unnecessary deaths.

The ARA also notes that the proposed measures to reduce the risks of intentional self-poisoning need to be evidenced-based and balanced with the need to ensure reasonable access to medication for consumers and households. We therefore recommend following the advice of the independent expert report. The experience gained from the COVID-19 pandemic has taught us much about surges in demand for essential items and we recommend giving careful consideration to potential unintended consequences of the proposed restrictions, particularly how they might impact on households in rural and remote areas where people may shop less frequently and not always have access to a broad range of retailers.

Further, we recommend that the proposed measures to restrict the sale of paracetamol are supported by safe reporting guidelines for health professionals regarding communication of the harms associated with overdose, improved after care support for intentional self-poisoning cases, as well as appropriate public health messaging, including promotion of safe-storage of medicine in the home and workplace.

ARA RECOMMENDATIONS

We make the following recommendations in relation to the proposed options outlined in the consultation paper:

	Proposed Option	ARA Recommendation
1	<p>Requirement for blister packs Solid dose paracetamol (tablets/capsules) only being available in blister packs for general sale</p>	<p>The ARA supports implementation of this option, noting that manufacturers will need sufficient notice and timeframes to make these changes.</p>
2	<p>Pack size restrictions Reducing paracetamol pack sizes to 10 x 500 mg tablets (currently 20 tablets) or 5 individually wrapped sachets for general sale. And for pharmacy only medicines, pack sizes to be reduced to 32 x 500 mg or 16 individually wrapped sachets).</p>	<p>The ARA supports the policy intention of restrictions on pack sizes, however, we note that the TGA's proposals go beyond the recommendations of the independent experts report.</p> <p>The ARA recommends following the report recommendations, for example, reducing the pack size to 16 tablets, rather than 10, for general sale.</p> <p>We also note that manufacturers will need sufficient notice to implement any changes to pack sizes and note the ongoing challenges our supply chains face.</p>
3	<p>Restrictions on purchase of multiple packs Limiting the sale of paracetamol to one packet per sale in non-pharmacy retail settings. In pharmacies limiting purchase to one pack without a prescription.</p>	<p>The ARA supports the policy intention behind restricting purchase of multiple packs, however, we note that the TGA proposal goes beyond the recommendations of the independent expert report. We also note that the data shows that the vast majority of sales are single pack purchases.</p> <p>The ARA recommends a limit of two packs in non-pharmacy retail settings and in pharmacies without a prescription.</p> <p>We believe a limit of two packs in these circumstances will achieve the policy intention of limiting access to amounts that could pose a risk, while also balancing accessibility for consumers, particularly those who may have limited access to retailers or a broad range of retailers, such as consumers in regional and remote areas.</p>
4	<p>Restrict sale of paracetamol to behind the counter.</p>	<p>The ARA recommends that this option is not implemented at this time. We believe the other measures provide a proportionate and sufficient response that will substantially reduce risk without the need for this measure.</p>

		<p>We note that this change will pose practical challenges (around merchandising and space at the point of sale) for retailers to implement this option, with costs likely to be significant. To ensure customers still have reasonable access to paracetamol with this restriction, retailers would likely need to invest in higher security display units and/or employ extra staff to assist with purchases. They would also need to train staff appropriately and broader customer education would be needed.</p>
5	<p>Age restrictions Restrict sale to 18+ years.</p>	<p>The ARA recommends that this option is not implemented at this time. We believe the other measures provide a proportionate and sufficient response that will substantially reduce risk without the need for this measure.</p> <p>We note that the medication is recommended for use in individuals aged 12 and over. While retailers could implement an age verification process for sale of paracetamol, this would be costly and would require significant changes at the point of sale, as well as require a public education campaign to inform consumers.</p> <p>Similarly to option 4, it also places paracetamol on the same footing as tobacco products or alcohol which could be a confusing message for consumers.</p>
6	<p>Modified release paracetamol restrictions – prescription only (S4) scheduling for this product.</p>	<p>The ARA supports implementation of this option.</p>

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