



Consumers Health  
Forum **OF** Australia

N

## SUBMISSION

Therapeutic Goods Administration – Consultation on  
Proposed Amendments to the Poisons Standard in  
Relation to Paracetamol

Consumers Health  
Forum of Australia  
(2022) Therapeutic  
Goods Administration –  
Consultation on  
Proposed Amendments  
to the Poisons Standard  
in Relation to  
Paracetamol, Canberra,  
Australia

**P:** 02 6273 5444

**E:** [info@chf.org.au](mailto:info@chf.org.au)

[twitter.com/CHFofAustralia](https://twitter.com/CHFofAustralia)

[facebook.com/CHFofAustralia](https://facebook.com/CHFofAustralia)

**Office Address**

7B/17 Napier Close,  
Deakin ACT 2600

**Postal Address**

PO Box 73  
Deakin West ACT 2600

## Contents

Consumers Shaping Health .....	3
.....	
Introduction .....	4
Consumer Insights Overview .....	4
Rescheduling Options.....	5
Blister Packs.....	5
Pack Size Restrictions.....	5
Pack Number Limits .....	6
Sale From Behind Counter .....	6
Age Restrictions .....	6
Modified Release (MR) Paracetamol Restrictions.....	7
Independent Expert Panel Non-Medication Specific Recommendations to Reduce Self-Poisoning .....	7

## Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interest of Australian healthcare consumers and those with an interest in healthcare consumer affairs. CHF works to achieve safe, quality, and timely health care for all Australians

At the heart of CHF's policy agenda is consumer centred care with access to and delivery of clinically safe and high-quality health care as key areas of focus.

CHF has undertaken consumer and peak body member consultations on the recommendations of the Independent Expert Panel into the risks of intentional self-poisoning using Paracetamol and the TGA Consultation paper on Proposed Amendments to the Poisons Standard in Relation to Paracetamol.

## Consumer Insights Overview

Overall consumers agreed with several options noting the importance of reducing levels of adolescent intentional self-poisoning. However, there was a strong view that the proposed changes, if implemented, would have a negative impact on access to a readily available and cost-effective pain relief tool for the whole community.

Consumers were also of the view that better definitive clinical evidence on the effectiveness of paracetamol, particularly in relation to pain such as that caused by arthritis, should be a component on decisions related to levels of access. This was a particular issue raised in relation to Modified Release (MR) Paracetamol

A key issue raised by consumers is that proposed restrictions on access, suggest a blanket nationally implemented approach. There was concern that specific exceptions, perhaps through regulation, should be incorporated to address access for all Australians. For example:

- those in rural and remote communities who need to purchase in larger quantities on a range of necessities due to geographic access. In this context consideration must be given to the likely higher costs due to limits on pack size and quantity.
- those who have existing medication access issues arising from a range of health and/or mobility issues
- and those who depend on a carer.

Education for both health providers and consumers was also highlighted as a key measure that needed to be incorporated into final recommendations. Specifically:

- Improved communication by doctors at all levels in relation to use of paracetamol. Experiences of contradictory advice between specialists and GPs were common.
- Improved communication and adherence to S3 dispense requirements in relation to MR paracetamol. Experiences of S3 medications being dispensed without question were noted.
- Enhanced packaging be required which identifies the risks, ideally in languages other than English.

CHF recommends that a national targeted health literacy package be developed. This package would use multiple channels and target at risk groups. Australians need to understand the risks of intentional self-harm that this review hopes to reduce if they are to be active partners in this reform. Such work should be consumer-led and include a mechanism to evaluate its efficacy.

## Rescheduling Options

### *Blister Packs*

CHF support in principle the switch to blister packs as part of the package to reduce misuse. We note the concerns of some consumers, especially those with conditions that reduce the dexterity and strength in their hands, that blister packs are not always easy to use. More work needs to be done with affected consumers to identify supportive options which would allow their continued use of paracetamol. Without such work, consumers may resort to mechanisms such as asking family members to un-blister large quantities for use over time. Such approaches would result in potentially perverse outcomes.

### *Pack Size Restrictions*

While in general terms CHF supports this option, consumers raised concerns related to affordability. The general assumption is that larger packs mean cheaper prices. They supported an option whereby pack sizes were reduced for general sale but larger packs to be available from pharmacies, behind the counter and/or with an age limit. There is an assumption that this recommendation would mean banning all non-blister pack larger quantity bottles (up to 100) currently available in some larger pharmacy outlets.

Consumers were also of the view that this recommendation would have limited value in addressing the issue to hand without implementation of pack number limits.

### *Pack Number Limits*

CHF supports this option with the caveat that it includes strategies aimed at avoiding critical access barriers for rural and remote communities, people with mobility disabilities and their carers. This may be addressed by access to larger packs and higher number of packs available from pharmacies for these groups of people.

### *Sale From Behind Counter*

CHF understands the intent of this option and supports it in principle as it could reduce impulse buying. Clearly this would need a process to be implemented in general retail similar to that used for selling tobacco products with no visibility for the consumer. Whilst this model works in pharmacy where staff can assist consumers to make a choice of product, it is unclear how this might work in general retail. Consumers' access to information at the point of sale is likely to be different depending on the context, and in some cases, consumers might need to make a choice of product based on little or no information.

It is also not clear how such options might be implemented in a digital sales environment. Currently consumer requests for over-the-counter medicines are managed differently depending on how medicines are requested (in store, over the phone, online) depending on the quality and safety mechanisms in place in each pharmacy.

### *Age Restrictions*

CHF supports this option but is of the view that the age range should be lowered to 16 or even as low as 14. There are many young people who are independent and capable of caring for their own health with their own Medicare cards and capacity to see health a professional without a parent or guardian adult present. There are also many young carers who would routinely purchase items such as paracetamol on behalf of their loved ones. Whether it be a young person or someone who relies on a carer, Australians should not be denied access to a legitimate short term pain relief. Young people are a key group to engage in the development of the relevant health literacy package.

Consumers noted that in the absence of access to a basic pain relief tool, there is a risk that alternatives that are currently unregulated, or even illicit, and available, will be sought. An age restriction that is too high was considered a risk in this context.

Combined with the Sale Behind the Counter option, it is assumed that where available as general sale a similar approach as that for sale of cigarettes would be imposed on all retailers.

### *Modified Release (MR) Paracetamol Restrictions*

The proposal that MR paracetamol be rescheduled to an S4 is not supported by CHF. Consumers unanimously agreed that remaining an S3 was currently adequate and that:

- Discussion in relation to use and dosage of the medication was more likely with a pharmacist than with a GP
- This medication is largely used by a different demographic to that which is the focus of the potential access changes.
- Any consideration to reschedule to an S4 should incorporate consideration of clinical evidence on its effectiveness in treating a range of pain related issues.
- Rescheduling to S4 has the potential to increase cost and negatively impact access.

## **Independent Expert Panel Non-Medication Specific Recommendations to Reduce Self-Poisoning**

In preparing this submission CHF also reviewed the Independent Expert Panel's Report to TGA. While not included in the TGA consultation paper we considered the non-medication specific recommendations as important and recommend they be included in implementation of changes to access to paracetamol. CHF's supports the following recommendations.

- Recommendation 5 – Use Safe Reporting Guidelines for Any Communication Around the Harms Associated with Paracetamol (or any other) Overdose.
- Recommendation 6 - Maintain and Expand Support for After Care Services
- Recommendation 7 - Inform Safer Storage of Medicines and Reduced Stockpiling of Unwanted Medicines