

## **Public consultation on proposed amendments to the Poisons Standard (paracetamol) - Advisory Committee on Medicines Scheduling**

Chronic Pain Australia and Australian Pain Management Association are providing a joint submission to the TGA in relation to the proposed restrictions to paracetamol. Our organisations represent the lived experience of Australian chronic pain.

### **We do not support any of the TGA's proposed restrictions to paracetamol.**

The community of people living with chronic pain continues to feel the burden of medication restrictions imposed on them without consideration of the financial impact and accessibility issues. The proposed paracetamol restrictions will negatively impact people with chronic pain, palliative pain, cancer related pain and end of life care who take these medications responsibly. If further medicine related restrictions are imposed on this community many will experience out of pocket costs from medical appointments and challenges accessing healthcare due to workforce shortages and extensive GP wait times.

Paracetamol SR has already been up-scheduled to a Schedule 3 medicine on June 1, 2020. Of the individuals who used paracetamol SR for intentional suicide only 10% were found to have used paracetamol SR. We would ask the TGA how they believe the medical profession could improve this rate if up-scheduled to a Schedule 4 medicine?

The TGA's submissions discuss the use of paracetamol preparations and make assumptions about the consumers who legitimately use these products for pain management (for example, most are prescribed for osteoarthritis). Paracetamol has shown no efficacy in the treatment of osteoarthritis. Most consumers use these products appropriately and for a variety of reasons, for example paracetamol:

- provides synergistic analgesia when combined with other analgesics for pain relief or flare up management
- opioid sparing benefits, typically reducing the Oral Morphine Equivalent dose by 10mg daily
- convenience and preference of slow-release formulations, reducing tablet burden and assisting with baseline pain management over 8 hours

We agree that many from the chronic pain community would see their GP on an ongoing basis, however placing restrictions on access to a medicine has the unintended consequence of increasing consumer costs and placing barriers to access. Paracetamol has an extremely well-established safety profile, with nil abuse potential. Paracetamol SR was previously available on the PBS for consumers with chronic pain conditions and now consumers are unable to access this subsidy.

If the TGA would like to place further restrictions on Paracetamol SR, we would propose an alternative that Paracetamol SR is made available on the PBS for chronic pain conditions so that consumers would have the price of the medicine subsidised.

**Chronic Pain Australia and the Australian Pain Management Association would like to impress upon the TGA the unintended consequences of medicine restrictions.** Opioid restrictions continue to have devastating impacts to the chronic pain community.

Chronic Pain Australia conducts the largest nation-wide survey. The *National Pain Survey 2022* has shown that Australians with chronic pain are unfairly stigmatised, are unable to access high quality health services, and the price of living with chronic pain is unaffordable. The consumer lived experience with opioid restrictions has meant that 26% of our survey respondents experienced enforced opioid tapering. 29% of respondents say their GP has put them on antidepressants, 28% on anti-inflammatories, 11% on sedatives, and 10% on medicinal cannabis as a substitute for pain relief. We know that drug induced deaths are caused by the combination of 4 or more substances, and it appears from our national survey that more patients with chronic pain are prescribed combinations of medications that could be more harmful in an effort to reduce opioids. Furthermore, it is well documented that enforce opioid tapering causes consumers to disengage from health care, seek medicines from illicit markets, worsens mental health and causes suicidal ideation.

Our point of discussing the impact of opioid restrictions is to highlight the importance that if there is no investment into quality pain management and mental health services, consumer education and self-management, placing restrictions on medicines only causes further harm.

The Australian Pain Management Association offers social support to people living with chronic pain, through our *Pain Support Group* network and our *Pain Link Helpline*. APMA regularly receives messages from our community about the barriers to accessing support within the healthcare system. We encourage self efficacy and self management, and know that having low cost and readily accessible paracetamol is a key component of managing pain.

Chronic Pain Australia and the Australian Pain Management Association support educating younger consumers about risks of overdose from paracetamol. Our community sees the impact of managing chronic health conditions, and the burden it places on mental health.

**We urge the Federal Government's Department of Health and the Therapeutic Goods Association to look broadly at the underlying mental health issues that contribute to overdose.**

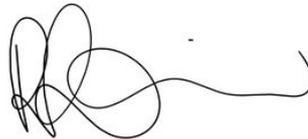
In response to the interim recommendations from the TGA, we canvassed our combined community for their views. 340 people responded to the survey which was opened for 48 hours. The findings show that consumers support education and awareness, but are concerned with restrictions that impact self management, affordability and access.

Should you wish to hear more about the impact the proposed changes would have on the 1 in 5 Australians who live with chronic pain – an often largely invisible illness - we are willing to provide a detailed briefing.

Yours sincerely



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#### **Community quotes in response to the survey:**

*"Yes, as someone with chronic pain its next to impossible to find a doctor to even listen let alone help you. Taking paracetamol and other over the counter pain relief would literally destroy my life and make me unable to care for my children."*

*"I can only use liquid paracetamol or paracetamol suppositories - which are infinitely cheaper purchased through reputable online pharmacies. This means I purchase multiple bottles/packs in one transaction to save postage costs - particularly important on a pension. The above changes would effectively double the cost of the paracetamol products I currently use."*

*"Yes as it will cost me more money to go to a GP for a script and wait time to get in to them for this as no GP locally bulk bills. The script for it may also cost more money. Better for a public awareness campaign about the dangers of taking too many paracetamol, especially when they are mixed in with other medications."*

*"Having to see a doctor to obtain a prescription for slow release Panadol would place extra strain on already overburdened GPs."*

Ages	Count
Under 18	2
18 to 25	12
26 to 35	21
36 to 50	117
51 to 65	137
66 to 75	39
76+	12

State / Territory	Count
QLD	64
NSW	93
ACT	12
VIC	82
TAS	11
SA	39
WA	38
NT	1

**1. Do you think reducing the size of packs of paracetamol sold in supermarkets and convenience stores, and in pharmacies without the advice of a pharmacist is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
220	50	33	17	20

*This recommendation imposes a duty of care on the shop owner. A reasonable proposition for purchases by minors, however this may not reduce the risk as many cases of harm are from medication used by others in the family, and depends of quantity purchased and multiple purchases from different locations.*

**2. Do you think limiting the number of packs of paracetamol products that can be purchased in one transaction to 1 or 2 packs to reduce home stockpiles of paracetamol is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
179	50	43	34	34

**3. Do you think making modified-release paracetamol, which is designed for long-term use rather than for acute pain, available only with a prescription is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
251	40	24	9	25

*We do not support this recommendation. Only 10% of overdoses are with modified release preparations. This would reduce access and increase cost (doctors visit and access issues) for legitimate use. A dose warning on the packet would be a reasonable option.*

**4. Do you think making modified-release paracetamol (i.e. Panadol Osteo), which is designed for long-term use rather than for acute pain, available only with a prescription is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
252	39	20	10	19

**5. Do you think restricting the purchasing of paracetamol without a prescription to individuals aged 18 years and older is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
199	32	45	31	33

*This recommendation is reasonable if the individual is purchasing more than a harmful dose, however, there would be impacts on retailers for proof of identity, staff training and display storage, the retailer could pass on the expense to the buyer. There are also limitations to this recommendation if the individual visits multiple locations to purchase smaller amounts, or takes medication purchased by an older person. Overall, this would be impractical to govern and the restriction is flawed as a motivated individual will seek from multiple locations, family, friends and community.*

**6. Do you think improving the communication around the potential harms from paracetamol is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
16	6	53	71	194

**7. Do you think maintaining and expanding follow-up care and support after self-harm is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
10	2	18	29	281

**8. Do you think increasing awareness about safer storage of medicines and reducing stockpiling of unwanted medicines is a sound recommendation?**

Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
15	17	44	70	194

*"Paracetamol is used safely and appropriately by the vast majority of users. Limiting access to one of the safest pain medications will not only lead to even more distress and cost for patients with chronic pain, but it will make life more difficult for everyday users who responsibly use paracetamol on an occasional basis. Don't punish the majority based on the behaviour of a minority. Increase education, funding and support for mental health issues. The ridiculously excessive limitations being put into on pain medication won't fix the core issues leading to misuse of these drugs and punishes a significant proportion of the population who use them responsibly."*