

painaustralia

Paracetamol

Submission on
proposed amendments
to restrict access



painaustralia



Panadol isn't the problem, it's the lack of mental health support. Making Panadol harder to access will only affect those that need it. If someone wants to self-harm by taking things orally, they will find a way.



~Painaustralia consumer

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Introduction

Painaustralia emphasises the importance of the Therapeutic Goods Administration (TGA) taking into consideration the contents of this submission as part of its consultation on proposed amendments to the Poisons Standard (paracetamol), to inform the November 2022 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

Painaustralia understands the aim of the proposed amendments in the Independent Expert Report on the risks of intentional self-poisoning with paracetamol to reduce intentional paracetamol poisoning, particularly in young people. Mental health is also an important issue that disproportionately affects people living with chronic pain, most of whom are beyond adolescent age.

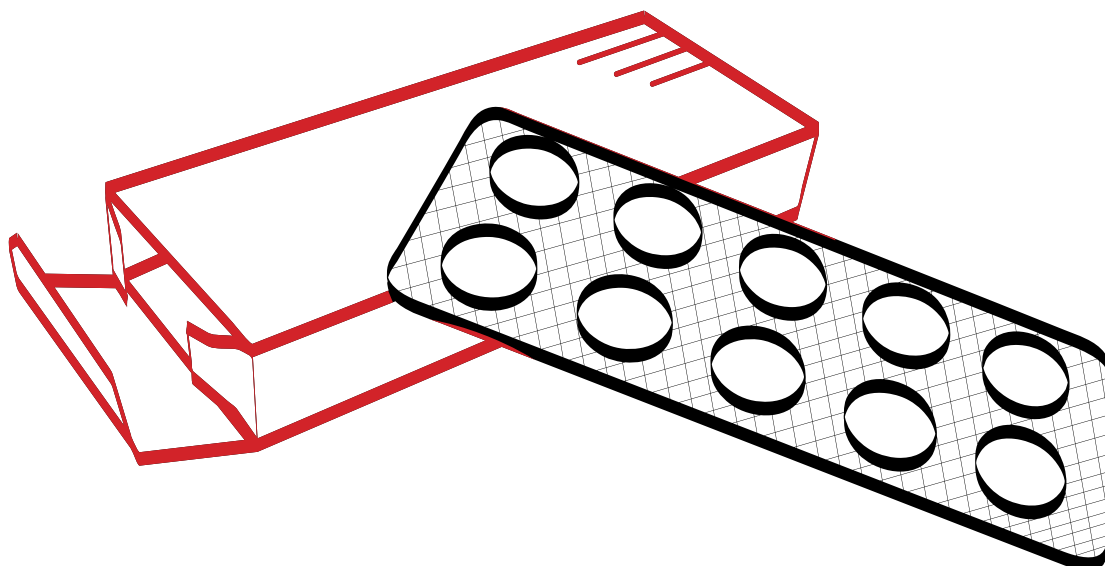
Painaustralia is concerned that the proposed amendments' narrow focus, while potentially benefiting hundreds of people who intentionally attempt to harm themselves with paracetamol each year, will negatively impact the millions of Australians who use paracetamol safely and in particular the 20% of the population living with chronic pain.

These changes are being looked at through the lens of mental health and not chronic pain, although it is clearly an issue about both and healthcare more broadly.

Mental health is not an issue that can be solved with a single regulatory **sledgehammer**. It needs a nuanced, balanced and practical approach that mitigates unintended consequences and guards against perverse outcomes of regulatory changes to ensure the best healthcare for all, including those living with chronic pain.

About Painaustralia

Painaustralia is Australia's leading pain advocacy body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain on individuals and the community.



Recommendations

1

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The TGA should work with consumers in revising or developing new proposals to ensure the impact of any restrictions is mitigated for people who use paracetamol safely.

2

Recommendation

Painaustralia would like the Independent Expert Panel to address any potential medication substitution because of these changes.

3

Recommendation

It is critical that the TGA develop an implementation plan which includes a clear communication and media strategy before implementing any changes. The plan should clearly outline how each change will impact consumers.

4

Recommendation

People who use paracetamol should have been involved in developing the Independent Expert Report's proposals and they need to be integral to deciding which changes are being implemented in the future. A review six and 12 months after implementation should also be conducted to determine the impact on consumers.



Background

Many people living with chronic pain choose to self-manage and paracetamol is one of the cheapest and most widely used medications for the 3.4 million Australians who live with chronic pain.

One in five Australian adults live with chronic pain (daily pain for more than three months).¹ Pain in general is prevalent, with 67% of Australians experiencing pain in the past four weeks, while around one in 10 Australians experience severe or very severe levels of pain.^{2,3}

The rates of chronic pain are on par with the prevalence of mental health in Australia,⁴ yet pain remains neglected and misunderstood as a public health issue.⁵ This is somewhat reflected in this consultation wherein the focus is clearly on addressing the outcomes of poor mental health, while ignoring that the solutions proposed will impact a significant number of Australians with chronic pain.

Pain conditions are widespread, with 30% of the population or 6.9 million Australians reporting arthritis in 2014-15, back pain was the third leading cause of disease burden in 2011 and one in 11 Australians reported osteoarthritis in 2011.⁶ Almost one in five of all GP consultations involved patients who had arthritis, chronic back pain or both conditions, irrespective of whether the condition was managed. Some pain conditions are more prevalent in rural communities, with people outside the major cities reported to be 23% more likely to have back pain, rising to 30% for residents aged 55 to 64.⁵

The chronic pain cohort will be significantly affected by the proposed changes - it is critical that the TGA understands this and develops new proposals before implementing potentially damaging reforms.



This submission presents real life evidence that comes directly from people who will be affected. It is based on information that was gathered through consultations with Painaustralia's Consumer Advisory Group (CAG) and a national survey of 100 consumers who will live with the impact of these changes every day.

The voice of consumers living with chronic pain are clearly reflected in this submission. They are telling the TGA that the proposed changes will not only limit their access to critical medication that helps them manage their condition, but as a result also cause unnecessary stress and anxiety that may also impact their mental health. They are also saying that improving health literacy and education and communication activities would be more effective in addressing paracetamol harm.

In considering any change to how paracetamol is regulated, Painaustralia requests that the TGA not shift the burden and outcomes of poor mental health from one cohort to another. There needs to be better understanding of the contributing and underlying factors that lead to intentional paracetamol poisoning, and of the cause and likelihood of success of proposed reforms, before any actions are taken.

These proposals must not be the only options available for consideration. The Independent Expert Panel **must** listen to the concerns of all consumers that will be affected by the changes and develop new proposals that will achieve the aim of reducing harm from paracetamol, without disproportionately affecting those who use paracetamol safely.

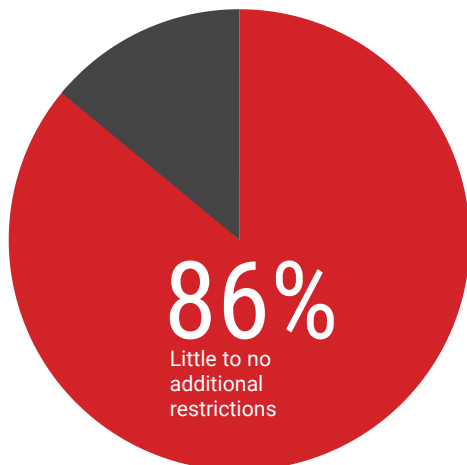


Painaustralia's Consumer Advisory Group and National Consumer Paracetamol Survey.

Painaustralia consulted its CAG and conducted a survey of 100 consumers who live with chronic pain about the proposals. Of those who participated, 75% were aged 60 and over, 88% were female and 96% use paracetamol.

Overwhelmingly, 86% of respondents believe that little to no additional restrictions should be placed on paracetamol. Of those that do believe there should be some restrictions, they do not support the restrictions as proposed.

When asked the question, *'Do you agree to any of the following recommendations from the independent panel to restrict access to paracetamol?'*, respondents had greater support for the enhancement of education and communication efforts instead of restrictions.



Survey results

1. Reducing the size of packs of paracetamol sold in supermarkets and convenience stores, and in pharmacies without the advice of a pharmacist. **Only 25% agreed.**
2. 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. **Only 31% agreed.**
3. Making modified-release paracetamol, which is designed for long-term use rather than for acute pain, available only with a prescription. **Only 11% agreed.**
4. Restricting the purchasing of paracetamol without a prescription to individuals aged 18 years and older – **Only 29% agreed.**
5. Improving the communication around the potential harms from paracetamol. **82% agreed.**
6. Maintaining and expanding follow-up care and support after self-harms. **77% agreed.**
7. Increasing awareness about safer storage of medicines and reducing stockpiling of unwanted medicines. **67% agreed.**

The consumer voice

Consumers living with chronic pain will, once again, feel neglected and forgotten if these proposals are passed. Recent history of poorly implemented regulatory changes relating to pain management treatments shows that this consumer cohort has been neglected and alienated by government. These proposals will only make matters worse unless consumer voices are listened to. Below are just some of the comments we received in response to the survey.

- “Most people use paracetamol safely. It’s an effective pain relief...People who are unwell will look at other methods. Educate people of the dangers instead. Will they go for ibuprofen next? I already find it hard to get into the doctors and can’t afford to pay for extra visits to get a prescription. To restrict it in this way is ludicrous because a very small percentage of people abuse it.”
- “My pharmacist already restricts me to one box at a visit. I would be significantly out-of-pocket if I needed to get a script to access this remarkable drug. The pain would kill me. I don’t intend to take an overdose. Give me some credit for being a rational adult, please.”
- “You have already restricted codeine, now you target paracetamol. How about putting it back onto the people. Taking simple paracetamol away is treating everyone like children. Responsibility and onus is on the person, not you. If people want to die, they will, no matter what drugs are taken away. All you are doing is making life so very very hard for people with a genuine need for pain meds.”
- “I think rather than restricting, that focussing on education is a better solution.”
- “If you live in a rural location it would massively affect you; we don’t all live in cities with doctors and pharmacies in every suburb.”
- “Personally, I use Panadol Osteo every day. The thought of having to see my doctor for a script just makes me heave an enormous sigh.”
- “You people physically make me sick! I’ve been suicidal over you being so strict and punishing those in actual pain over the use of opioids - all because a chosen few misuse. And now trying to attempt to restrict Panadol? Maybe employ someone in actual pain on your so called ‘board’.”
- “People in pain have no quality of life now, because of irrational restrictions on opioids, remove access to paracetamol, and you will see a dramatic increase in suicide due to no hope for those in chronic pain. The use of mental health drugs for pain is far more dangerous, and that is proven by multiple overseas studies.”

- “Any young woman (15-18) would be very upset to find they couldn’t slip into a Coles to get some Panadol for her period pain. I grew up without a mother and the thought of having to ask a father to get me Panadol would have been mortifying”
- “I do not support upscheduling of modified-release paracetamol; it would introduce too many barriers to access.”
- “Restrictions have a 100% failure rate. Every time these are imposed, we have a statistical increase in illicit drugs, alcohol or other prescription drugs... It doesn’t make it safer, it

moves the problem to somewhere else.”

- “My preferred approach is an industry-funded high-profile, longer public education, plus pharmacists taking a more educative role.”
- “Let’s treat the issues behind misuse, addiction. Not punish the people who use correctly.”

The following consumer comment sums up one of Painaustralia’s key positions:

“Panadol isn’t the problem, it’s the lack of mental health support. Making Panadol harder to access will only affect those that need it. If someone wants to self-harm by taking things orally, they will find a way.”



Recommendation

The TGA should work with consumers in revising or developing new proposals to ensure the impact of any restrictions is mitigated for people who use paracetamol safely.



Painaustralia's response to the proposals

Below are Painaustralia's responses to each proposal and a summary of consumer issues that should be considered as part of this consultation.

1. Pack size restrictions. For example, maximum pack sizes for unscheduled products reduced from 20 to 12 or 16 tabs; S2 pack sizes reduced from 100 to 24 or 50.

Our Response

We do not support this proposal. Reducing unscheduled and S2 pack sizes would result in people needing to visit the supermarket or pharmacist multiple times a week or more frequently.

3. MR paracetamol restrictions. This product is designed for long-term use (eg. for osteoarthritis), rather than for acute pain. Prescription only (S4) scheduling would be expected to reduce casual use of this more dangerous product and therefore overdoses.

Our Response

We do not support this proposal. The evidence is inconclusive that this proposal would reduce overdoses. What is certain is that it would add time and financial costs to consumers who wish to access MR paracetamol who, for the large majority, use it safely. Further, recent changes including upscheduling have been in place for less than two years, which is too short a time to measure their effect. There are also any additional costs at the pharmacy for the consumer, not just the GP consultation, which is free in the UK, that must be considered.

2. Pack number limits. Most (~95%) sales of paracetamol tablets involve the purchase of 1 or 2 packs. Making this the maximum number of packs that can be purchased in one transaction would almost certainly reduce home stockpiles, and likely also reduce the number of very large overdoses, which have much higher morbidity and risk of death.

Our Response

We do not support this proposal. This creates an impediment to self-management of chronic pain that is burdensome for consumers, particularly those who have low incomes or with limited transport options, including those who live in rural and remote areas.

4. Age restrictions. An 18+ age restriction on the purchasing of over-the-counter analgesics would be expected to reduce poisonings among 10-17 year-olds.

Our Response

We do not support this proposal. Notwithstanding that this would negatively impact young carers who provide support to adults, this policy places the same requirements on accessing paracetamol as alcohol or tobacco which are clearly more harmful in general to society.

Proposals 5-7.

The Independent Expert Report does not provide detail into how these proposals will be implemented. While Painaustralia agrees in principle, the TGA and other relevant stakeholders would need to clearly outline a plan, specific actions and metrics for how these efforts will impact consumers.

- 5. Use safe reporting guidelines for any communication around the harms associated with paracetamol (or any other) overdose. Any communication around the potential harms of paracetamol must comply with safe reporting guidelines and be rigorously evaluated prior to implementation.***
- 6. Maintain and expand support for aftercare services. All intentional self-poisonings should be offered appropriate care and Australian recommendations for aftercare (follow-up care and support after self-harm) implemented.***
- 7. Inform safer storage of medicines and reduced stockpiling of unwanted medicines. Generic messages around keeping medications and chemicals out of harm's way might reduce intentional poisoning risks for children and adults.***



Summary of Key Issues

Outlined below are key issues relating to the proposals that the TGA/ACMS must consider before making changes to how paracetamol is regulated.

Out-of-pocket costs

Medicines are the cheapest and easiest form of therapy to access in treating and managing chronic pain and paracetamol is one of the most cost-effective pain management therapies available to consumers.

Painaustralia is concerned that the proposed changes will result in price increases by sponsors and additional access costs for consumers. For example, proposal 3 to upschedule MR paracetamol would result in the consumer paying for an additional GP consultation every time they need a prescription.

Proposal 1 and 2 to reduce pack sizes and apply limits, respectively, may result in the consumer having to visit the supermarket or pharmacy 2-4 times a week. For consumers who live in rural and remote areas the additional cost of their time and fuel makes these changes particularly burdensome.

For consumers who are unemployed or who have low incomes, the cost of extra trips will mean many will go without their medication. These proposals hit the poorest the hardest.

Can the TGA provide price certainty for consumers or will these changes increase the price per tablet of paracetamol?

The Independent Expert Report notes that several international jurisdictions have implemented restrictions on paracetamol that have had a positive effect in reducing the number of tablets taken in attempts and the severity of poisonings, such as in the UK where GP visits are free. But the Independent Expert Report also notes that there are limitations when trying to assign equivalent Australian schedules against the scheduling categories in some overseas jurisdictions.

The effectiveness of the UK example noted in the Independent Expert Report, for example, where restrictions similar to what is proposed in Australia have been implemented, do not have a category for MR paracetamol and may benefit from the GP consultations being completely free.

For many living with chronic pain in Australia, access to or eligibility for bulk billing doctors is simply not available and consideration needs to be given to nuances and realities for the Australian consumer.

And while restrictions such as those proposed may have led to a decrease in deaths involving paracetamol and a reduction in the toxicity of intentional drug overdoses, restrictions in pack size have not reduced the frequency of intentional paracetamol overdoses, with Ireland still having one of the highest incidences of such in Europe.⁷ This raises an important question of why they are being considered if they have limited effectiveness.

Flow on effect: on-costs to the health system

The additional costs to the health system as a result of up-scheduling MR paracetamol needs to be considered. Government will also pay more and GPs are already considered scarce. Painaustralia does not support up-scheduling of MR paracetamol.

Additional out-of-pocket costs

- Consumers' current out-of-pocket costs for GP consultations to purchase schedule 3 MR paracetamol: \$0 per year.
- Consumers' future out-of-pocket costs for GP consultations to purchase schedule 4 MR paracetamol: **\$600 per year.**



Timeliness

Medicines remain the most accessible and affordable treatment option to manage chronic pain. The wide availability of drugs such as paracetamol and ibuprofen make them the primary choice for pain relief for anyone experiencing pain.

Despite the belief of some involved in implementing the proposals, consumers may not live in affluent metropolitan areas with plenty of access to late night supermarkets and pharmacies, and would therefore have their access limited.

The scarcity of pain specialists nationwide and long wait times, combined with the need for greater consumer and health professional awareness about better approaches to pain management, means consumers have few options to turn to besides opioids or alternatives such as paracetamol.

The flow on effects of these proposed changes must be considered before any are implemented.



Recommendation

Painaustralia would like the panel to address any potential **medication substitution** because of these changes.

- If consumers are forced to see a GP just to get a prescription for paracetamol, has the panel considered the flow on effects of consumers seeking other pain medications instead?
- Given the changes to opioid regulation in 2020 for safety reasons, will these proposals result in a perverse outcome of consumers opting to stronger analgesics instead?
- Will these proposals result in consumers turning to illicit cannabis, alcohol and other drugs to manage their condition?



Gaps in the Independent Expert Report

Painaustralia has concerns about gaps or unknown factors which the proposals may be based on and whether the proposed reforms will have the desired impact.

Hospital admissions for paracetamol poisonings appear to remain unchanged significantly over the past 10 years and have been declining from 2017. And while there has been a general increase in paracetamol poisoning events, this has predominantly been driven by females aged between 15-19.

There needs to be better understanding of why this affects a specific cohort, and any proposed reforms should benefit those most affected. It is unjust to unnecessarily impact a majority who use paracetamol safely.

The Independent Expert Report does not appear to address why differences in cohort trends exist and why adolescent women are more affected; the fact that intentional poisonings across all medicines are increasing, but the proportion attributable to paracetamol may have fallen; and, why the figure of deaths per year is undefined ranging anywhere up to 50 deaths per year.

While such foundational data is unknown, any subsequent actions may result in poorly targeted and ultimately ineffective measures, or perversely may make the situation worse.



Dwindling Healthcare Treatment Options

Medicines are often the mainstay of treatment to treat pain and medicines such as paracetamol play a significant role. However, there is a trend in therapeutic goods reform recently that threatens and has limited medication options for people living with chronic pain. First codeine was upscheduled, then opioids and now paracetamol may be harder to access.

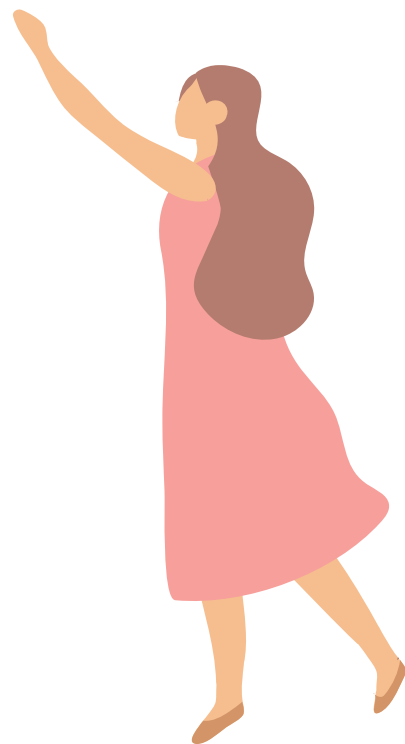
The proposals and the Independent Expert Report don't appear to understand and address the underlying causes of intentional paracetamol poisoning in the cohort that it greatly affects. People living with chronic pain are already in distress, anxious and have limited treatment options. The TGA needs to understand that these changes will have a detrimental impact on a large and vulnerable cohort. Many consumers have commented that some will be driven to find and use illegal drugs instead or turn to stronger pain medications as result.

The Australian Government introduced regulatory changes to the prescription of opioids as well as access to Modified Release Paracetamol for the management of pain. These changes came into effect from 1 June 2020 and were part of a suite of measures intended to support appropriate use of opioids, multimodal medicines and other pain medications, changes to clinical guidelines, and ongoing prescription and compliance monitoring.

These changes **coincided with the pandemic** and the **national rollout of Real Time Prescription Monitoring programs**. All these factors have contributed to limiting consumer access to medications.

At the same time there are few accessible and affordable alternative treatment options being supported by government, such as funding for multidisciplinary pain management services and Medicare items for chronic pain. Limiting access to paracetamol, on top of the recent opioid restrictions, **is another nail in the coffin** for people wanting to self-manage their condition.

The Government cannot continue to further restrict access to pain management medication under the guise of safety without recognising that the outcomes result in poor mental health and health outcomes for people living with chronic pain.



The Unintended Consequences of the Opioid Reforms

There are lessons to be learned from recent history with the implementation of the opioid regulatory changes.

Painaustralia conducted a consumer survey on the impact of the opioid regulatory changes⁸ and received an overwhelming response with more than 1800 respondents. Since the reforms were introduced, a total of 37.7 per cent of respondents said their opioid medication had been reduced by a health professional and total of 18.5 per cent had their medication ceased. Sixty-one per cent of respondents who had their medication ceased or reduced said they would like to be more involved in the decision regarding their medication.

In this review, consideration should also be given to the **human right to equitable access to medicines and health care**.

Proposing to limit consumers access to basic medication, without being consulted or consenting in the design process, ignores their rights to reasonable expectation of supply.

Consumers' agency over decisions affecting their health should also be a critical factor underpinning medicines regulation change.

Consumer responses to Painaustralia's survey:

I was given no warning at all and I can still tell you there are people in Australia today who don't even know that changes were made, people still go to their GP's in pain thinking they will be able to prescribe adequate pain medication.

When you advise them you are in constant pain and you need solutions, they say the government rules prevent them from assisting.

Since the change I have increased anxiety about being able to manage my pain and access services to continue treatment. Also, the cost of these supplementary medications and treatments is far higher.

Many respondents were concerned that their medications had been stopped or were reluctant to go to a GP in case their medication was ceased immediately. There were also reports of rapid opioid tapering with a lack of support or guidance from their prescribing health professionals. Rapid opioid dose reduction is a concern as it can pose risks such as more severe pain and neuropsychological effects.

These outcomes were predicted and were stated and recorded in every meeting of the TGA's Opioid Regulatory Advisory Group. Painaustralia warned the TGA of the need to present tangible alternatives which were ignored in the roll out, which had devastating impact on the mental health of consumers who were on the affected medications.

Recommendation

It is critical that the TGA develop an implementation plan which includes a clear communication and media strategy before implementing any changes. The plan should clearly outline how each change will impact consumers.



Overwhelmingly, survey respondents reported they were worse off since the introduction of the opioid reforms. When asked to compare their chronic pain condition in the 12 months before the opioid reforms (June 2019 to June 2020) and the 12 months after the reforms (June 2020-2021), over half of the respondents (52.5 per cent) said the management of their chronic pain had worsened in some way. Only 5.6 per cent said it had improved. A majority 53.3 per cent attributed their worsening pain to the opioid reforms negatively impacting on their quality of life.

This is an example of where changes were not implemented properly and had unintended and harsh outcomes, further exacerbating the issues faced by people living with chronic pain. Painaustralia implores the TGA not to repeat the same mistake.

Recommendation

People who use paracetamol should have been involved in developing the Independent Expert Report's proposals and they need to be integral to deciding which changes are being implemented in the future. A review six and 12 months after implementation should also be conducted to determine the impact on consumers.

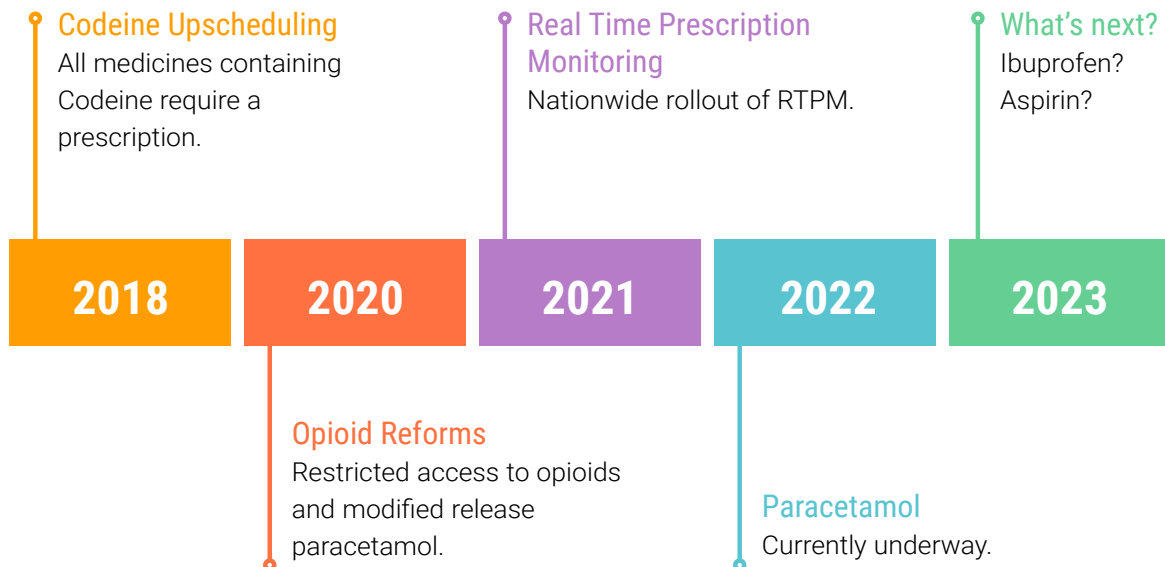


Previous Regulatory Changes

Since 2018, when codeine was Upscheduled, we have seen a trend of reforms which have further eroded available treatment options for this cohort. Many consumers are wondering which of the pain management treatment options are next to be restricted. The Government's actions are creating an **environment of fear** which could lead to stockpiling amongst consumers.

The TGA needs to consider the compounding effects of these reforms at a nationally stressful time during the pandemic and how restricting access to paracetamol will result in even fewer low cost and easily accessible treatment options for already vulnerable consumers living with constant pain.

Figure: Regulatory changes resulting in fewer treatment options. What's next?





Consumer Input Essential

The expertise of the panel who drafted the Independent Expert Report is to be commended, however, consumers must be involved from the very start of any health regulatory change process.

Painaustralia believes that consumers should have been more extensively involved or consulted prior to the Independent Expert Report being released.

Consulting consumers living with chronic pain would have brought to the light the various issues and impacts of the proposals for this cohort. Solutions to reduce the prevalence of intentional paracetamol poisoning could have been developed that would not have resulted in unintended outcomes for consumers.

Painaustralia highlights the importance of a chronic pain consumer voice needing to be on or informing the panel; one that is clearly representative of people for which the drug in question is indicated. The TGA should consult more with consumers to understand the downstream impacts of regulatory changes.

Conclusion

While we support the aim of the proposals contained in the Independent Expert Report, more data, consumer consultation and consideration of unintended consequences is needed before changes are made. New proposals must be developed with the help of consumers who will be affected which will in turn support their human right to have control of their pain management and healthcare.

Mental health is an important issue that needs a nuanced approach rather than the narrow, regulatory sledgehammer currently proposed. The hundreds of people who intentionally attempt to harm themselves with paracetamol each year

need support and the public needs greater education and awareness about potential harms relating to paracetamol. The changes must focus on providing this while not negatively impacting the millions of Australians who use paracetamol safely as a result. This is a mental health issue and a broader health issue.

Painaustralia appreciates the opportunity to provide input into the TGA's public consultation on proposed amendments to the Poisons Standard (paracetamol) and welcomes the opportunity to be further involved in developing solutions to address paracetamol harm. We stand ready to assist with consumer consultation at any time.



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painaustralia

Working to prevent and manage chronic pain

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