

Speech to the Medicines Scheduling Advisory Committee on 16 November 2022.

A. Introduction to Painaustralia

Good morning. I am Giulia Jones, the CEO of Painaustralia.

3.4 million Australians live with chronic pain. Those living with Chronic pain suffer not only daily pain but a sense of loss of functionality which has been impaired, they also regularly experience being mocked, belittled and ignored because their invisible distress is considered by many to be made up, or an exaggeration.

Painaustralia has a significant social media following reaching an audience of more than 50,000 people living with chronic pain and their networks, we have over 20,000 hits to our website per month and are closely networked with medical professionals and their representative bodies as well as our own clinical advisory council.

B. The problem of pain

Pain causes emotional, physical, and mental distress as well as loss of independence, confidence, and income and strained relationships. This means that we as a society we have a very high obligation to do better at listening to them, respecting them and properly considering the lives that they have to live to get by, to keep body and soul together.

Forty five percent of Australian adults with chronic pain also experience a high level of psychological distress and **are 2-3 times more likely to be suicidal than those without pain.**

A. Mental health issue

We know there were suicides associated with the changes 2 years ago to the availability of opioids and the deprescribing of consumers who had no other treatment options offered to them – restricting another treatment option for this group could result in even more such self harm. The proposals we are dealing with today has the very real potential therefore to shift the burden of mental distress and suicidality from one vulnerable cohort to another.

When those with chronic pain die by suicide from the anguish and loss of hope from their condition, the cause is not attributed to their chronic pain. No death certificate says, died from suicide caused by chronic pain and mental distress, but we know it is happening. This cohort is even more vulnerable to this outcome after huge access changes which were rolled out during the pandemic, which saw everyone in the nation isolated and restricted. On top of the pain they were already dealing with day by day.

A. What our consumers are saying:

Painaustralia upon receiving the report, conducted a survey of 100 people and consulted its consumer advisory group on their views on the proposals.

Overwhelmingly 86 per cent of respondents stated that no restrictions should be placed on paracetamol. Of those that do believe there should be some restrictions they did **not** support the restrictions as proposed.

Some of the comments we received included:

1. "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."
2. "Let's treat the issue behind misuse, addiction, Not punish the people who use it correctly"
3. "To make something like paracetamol accessible via a script only will only add an extra and unnecessary expense for the people like myself who really need and rely on this. This system creates an extra doctor visit which some people cannot afford and extra time out of their day which chronic pain sufferers cannot deal with."
4. "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. I busted my butt trying to get off of an opioid and the other pain medication. I don't want a script to manage my pain. It feels like a setback. I buy the

Panadol Osteo over the counter from my regular pharmacist. She helped me taper off of opioids”

5. “Its hard enough to afford my paracetamol, I am on jobseeker and I need to buy it on pay day or I run out of money long before my next pay comes in.”

These comments show how important it is to listen to consumers.

B. The Need to listen to consumers

The independent panel making the recommendations consisted of three academics with expertise in pharmacology, toxicology and mental health. There is no consumer on the independent expert panel that conducted the review. As a result of no consumer expert being included in the expert group, the focus of the review is limited and the impact and unintended consequences that further victimise and demonise an already vulnerable cohort of people, the 3.4 million Australians living with chronic pain far outweighs any benefits which are suggested.

C. Access to GPs / Access to Medicines / Cost \$

Medicines remain the most accessible and affordable treatment option to manage chronic pain. Appropriate access to paracetamol is considered by many pain specialists to be essential for patients living with chronic pain. Paracetamol for pain management is recognised by the World Health Organisation and is one of three non-opioid analgesic medicines in its Model List of Essential Medicines. And when used appropriately it is a safe medicine.

The scarcity, long wait times and costs of other treatments such as pain specialists and multi-disciplinary care means consumers, especially those on low incomes, young people and those living in rural or remote areas have few options to turn to besides paracetamol.

In addition, many people with conditions such as high blood pressure and stomach ulcers can't take aspirin or ibuprofen. Paracetamol is all that they have.

D. Mental health of young women

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 young women aged between 15-19.

There are around 30 deaths per year caused by paracetamol overdose. Those who survive are treated with an antidote in our emergency departments but if they turn to other medicines or methods the outcome for them could be far worse.

It is my understanding that in Ireland after restrictions were implemented, the suicide rate among the target cohort actually increased. It is a very serious matter if attempts to improve something actually made it worse.

There needs to be a better understanding of **why** young women are using paracetamol in this way, and any proposed reforms should be targeted to benefit those most affected.

These proposed reforms do not address the problem of young women who are suffering from mental distress and seeking relief from their situation, Minister for Mental health is far better informed and in a position to address this issue in a meaningful way.

Instead, we should be looking at the issue as a whole providing proper psychological support to this cohort, following up with people who attempt suicide when they are in still in hospital, and after discharge.

Additional education and funding for mental health services is needed – not more regulation that will not magically solve the actual problem of suicidality amongst young women.

E. Cost

Painaustralia is concerned that any changes to paracetamol will result in price increases for consumers. For example the proposal to upschedule modified release paracetamol would result in the consumer paying for an additional GP visit every time they need a prescription. Smaller packs may well mean a higher cost per tablet as well.

F. Recent History – tough on consumers. Opioids. Codeine.

At the same time as the pandemic hit those living with chronic pain have been asked to learn to live without codeine access and then without opioid access on the whole. And though many have done this willingly, many are very aggrieved by the changes to the options they have making fewer and fewer options for treatment available.

Codeine was up scheduled in 2019, followed by the opioid reforms in 2020 – reforms that were badly managed and implemented. At every meeting of the Opioid Regulatory Advisory Group Painaustralia and others raised the need for alternative treatments to be offered to consumers at the point of changes to their prescriptions from opioids.

But we know from the very many distressed consumers we hear from that when they lost their access to opioids, no alternatives were offered, and many live with paracetamol as their only viable option to manage their pain.

Paracetamol osteo was up-scheduled to behind the counter in pharmacies in 2020. I have been told in a letter from the health minister that the TGA regularly reviews such changes to scheduling after 2 years with the data which has been collected. The 2 years of data has not yet been analysed therefore any decisions about slow-release paracetamol here are being made without even the basic analysis of the **last** changes and how they have affected consumers and usage.

Just like the paracetamol review, the opioid reforms focused solely on regulation rather than alternative policies and solutions to provide treatments for people who live with chronic pain.

These latest proposals will compound the many challenges faced by people living with chronic pain. Restricting access to paracetamol will result in even fewer low cost and easily accessible treatment options.

G. The proposal:

Therefore, Painaustralia does not support the first four of the panel's seven recommendations and instead recommends that the TGA revise any

recommendations from the very beginning with the involvement of consumers.

Rec 1: Proposes to reduce the size of packs of paracetamol sold in supermarkets and on open pharmacy shelves to 16 tablets per pack – This unduly impacts people on low incomes who often buy their paracetamol on payday – for those very safely taking 6-8 paracetamol tablets per day, this will mean a packet only lasts for 2 days.

Rec 2: Limiting the number of packs of paracetamol products that can be purchased in one transaction to 1 or 2 packs would provide only 4 days of supply – not everyone lives close to a supermarket or pharmacy or can access these shops every few days. For many of the chronic pain cohort every outing is an ordeal.

Rec 3: Restricting the purchasing of paracetamol without a prescription to individuals aged 18 years and older – discriminates against young carers picking up paracetamol for their family members, and young women who have chronic pelvic or period pain. For young independent people who live out of home before the age of 18 because they do not have anywhere else to live, for them this is a disaster.

Rec 4: Making modified-release paracetamol, which is designed for long-term use rather than for acute pain, available only with a means the cost of and wait for a GP appointment, especially in this era when we have a GP shortage.

Rec 5, 6 and 7: Painaustralia does support proposals 5, 6 and 7 to improve the communication around the potential harms from paracetamol, maintain and expand follow-up care and support after self-harm and increasing awareness about safer storage of medicines and reducing stockpiling of unwanted medicines.

H. What we really want to see: Consumer involvement in design

Painaustralia would like the TGA and any expert groups that are set up to look at particular medicine groups and their supply to include relevant and strong consumer expertise so that proposals are not made which will impact so harshly on already mentally distressed and struggling chronic pain consumers when the intention is to help vulnerable people.

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

While we support the aim of the review, more data, consumer consultation and consideration of any unintended consequences and flow on effects on people with chronic pain must be considered before ANY changes are made. We support education about safe storage of medicines in the home which is going to change the access young people have to medicines that are much needed by other members of a family.

We urge the TGA to raise the concerns about vulnerable young women with the Minister for Mental Health Emma McBryde who is equipped and empowered to address mental health needs of young women. But to allow those in pain access to this safe medicine which is all many of them have left to assist with their pain every single day.