



Global Healthy Living Foundation Australia
Tower 1, Level 2,
495 Victoria Avenue, Chatswood, NSW 2067
ABN: 82 609 039 134
+61 439 600 312
info@ghlf.org.au
www.ghlf.org.au



Global Healthy Living Foundation Australia and CreakyJoints Australia

Submission for the Therapeutic Goods Administration proposed amendments to the Poisons Standard in relation to paracetamol

Re: TGA – Why we are consulting:

https://consultations.tga.gov.au/tga/paracetamol_november_2022_acms/consultation/subpage.2020-08-24.4118714205/

About Global Healthy Living Foundation (GHLF) Australia and CreakyJoints Australia

[GHLF Australia](#) is a not-for-profit organisation founded in 2015. GHLF Australia is part of the US-based Global Healthy Living Foundation (GHLF), a non-profit organisation whose mission is to improve the quality of life for people with chronic illness.

GHLF Australia is the parent organisation of [CreakyJoints Australia](#) (CJA), the vibrant online patient community which connects arthritis patients with current and relevant disease-specific information and support across a spectrum of arthritis conditions (of which there are more than 100), using a diverse set of digital platforms.

GHLF Australia aims to localise, mobilise and engage the Australian patient and caregiver community and to provide education, advocacy and research for better health outcomes.

About our members

Our members include people of all ages and genders with a diverse spectrum of cultural and linguistic backgrounds. Many live with financial strain due to the cost of regular medications, health appointments, restricted mobility and reduced earning potential.

Most of our members live with chronic, often painful, conditions and many use paracetamol products as part of their regular pain management regime. Through anecdotal conversations with our members, along with comments on our social media posts, we believe that those who use paracetamol products do so responsibly — within the recommended daily limits and under the supervision of their treating doctors.

It is important to note that people with chronic pain generally use a wide range of tools to manage their pain and maintain a reasonable quality of life. These include medications but also non-medicinal tools such as exercise, physiotherapy, heat packs, yoga and more. Also, many of our members deal with multiple sources of pain that may vary in intensity and frequency at different times.

Some examples of how our members use paracetamol products include:

- In low, occasional doses to manage pain from flare-ups of their chronic condition in between sustained periods of little or no pain or to manage acute pain from other conditions, such as headaches.
- In moderate doses or forms (such as two to six tablets of 500mg paracetamol or two to four tablets of modified-release paracetamol) daily to help keep their pain at a steady and manageable level, with or without other pain medications.
- In high doses (such as the maximum recommended dose of 500mg paracetamol or MR paracetamol) daily to manage strong pain. This may be only during flare-ups or ongoing, especially if they can't use or access other forms of strong analgesics (such as opioids) or disease-modifying anti-rheumatic drugs.
- Some people use both 500mg paracetamol tablets **and/or** 500mg paracetamol/15mg codeine tablets to manage pain. For example, they may take alternate doses of paracetamol only and paracetamol/codeine tablets or they may take one paracetamol only tablet plus one paracetamol/codeine tablet per dose. We believe most people who do this take care to ensure they don't exceed the maximum recommended dose of 4,000mg of paracetamol/day.

We are aware the TGA is also currently considering down-scheduling some modified release ibuprofen from Schedule 3 to Schedule 2. This would allow people to access these products from the shelf at pharmacies without prior consultation with a pharmacist.

We understand ibuprofen has an equivalent or better risk profile than paracetamol and aspirin so it may be more appropriate for some people to use it for pain management. However, many people with chronic inflammatory conditions, such as ankylosing spondylitis, already take other NSAIDs regularly. Therefore, it would be a contraindication for them to also take ibuprofen for pain relief and they could not use ibuprofen as an alternative to paracetamol products.

General feedback about the Independent Expert Report and the online submission form

Independent Expert Report

We noted the authors of the report included experts in pharmacology, toxicity, mental research, systematic review design and representatives from the Black Dog Institute. This is an appropriate mix of health experts and mental health lived experience representatives. However, we were concerned that pain management experts and consumers with chronic pain were not represented. This was a missed opportunity.

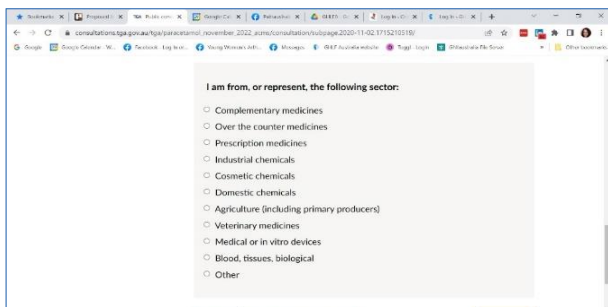
We believe people with these backgrounds could have made significant contributions to the discussions about all the study's aims and these aims in particular:

- *Critically analyse the balance of the benefits and risks of the current access to paracetamol on the Australian market in relation to intentional self-poisoning, particularly in regard to paracetamol available by general sale.*
- *Discuss the possible outcomes in the community of restricting general sale access or purchasing controls to paracetamol, including deliberate self-poisoning with other medicines.*

Online submission form

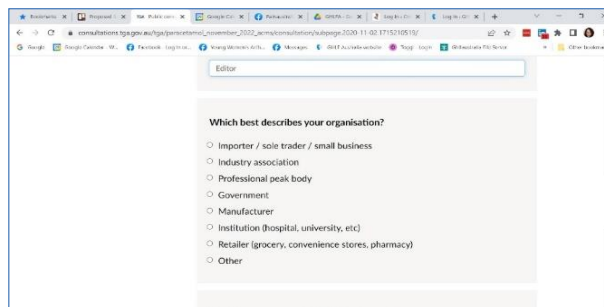
We noted that the online submission form did have an option for people to select if they were responding as an individual or as a representative of an organisation. However, the items related to industry sectors and organisation descriptions did not provide any options for health consumer organisations that are not peak bodies.

There are many non-government organisations such as ours, representing people with a broad scope of chronic health conditions that appear to have not been considered in the design of this form.



I am from, or represent, the following sector:

- Complementary medicines
- Over the counter medicines
- Prescription medicines
- Industrial chemicals
- Cosmetic chemicals
- Domestic chemicals
- Agriculture (including primary producers)
- Veterinary medicines
- Medical or in vitro devices
- Blood, tissues, biological
- Other



Editor

Which best describes your organisation?

- Importer / sole trader / small business
- Industry association
- Professional peak body
- Government
- Manufacturer
- Institution (hospital, university, etc)
- Retailer (grocery, convenience stores, pharmacy)
- Other

Finally, we were also concerned there was no plain language summary of the report or related web pages and the survey questions were not available separately as a downloadable document. As a result of these oversights, we believe people with lower health or computer literacy, people with technology access needs or people from linguistically diverse backgrounds would have difficulty accessing the report and responding to the survey.

We trust you take this constructive feedback in the spirit it is intended and use it to improve future reports and surveys.

Our response to the TGA proposals on the proposed amendments to the Poisons Standard in relation to paracetamol

Option 1

Option 1A – Solid dose paracetamol (tablets/capsules) should only be available in blister packs for general sale preparations.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

We can see an argument for retail outlets other than pharmacies or supermarkets (such as service stations) to offer paracetamol products in blister packs — perhaps also with a maximum of 24 x 500mg tablets/pack. This may help reduce the number of tablets available for spontaneous purchases by people with acute pain or those seeking to self-harm.

Option 1B – Solid dose paracetamol (tablets/capsules) should only be available in blister packs for general sale and in pharmacies.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

We support blister packs for general sale and pharmacies, however, people who need larger quantities for chronic pain should be able to access bottles on prescription or OTC at pharmacies.

Many people with musculoskeletal conditions that affect their hands struggle to open blister packs. It is important to have different packaging types (such as plastic screw-top jars) available so that everyone who needs paracetamol products can physically open the packaging.

Option 1C – Solid dose paracetamol (tablets/capsules) should only be available in blister packs from all points of purchase.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

As above

Option 1D - All solid dose preparations of paracetamol, including prescription and non-prescription preparations.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

The wording of this option does not appear to be complete and there are no accompanying notes for it in the [Pre-meeting Public Notice – Paracetamol](#) document. Therefore, we were unable to provide any comments about it.

Option 2

Option 2A – The maximum paracetamol pack size should be reduced to 10 x 500 mg tablets/capsules or 5 individually sachets for general sale preparations.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

We support the idea of reducing the pack size to 10 tablets/5 sachets in general. However, we note this may not be enough in some circumstances. For example, a parent buying paracetamol for the whole family if they have COVID-19, travellers in remote areas needing to carry a moderate bulk supply or people with acute conditions that could last a few days but who can't get to a pharmacy easily.

Option 2B – The maximum paracetamol pack size should be reduced to 32 x 500 mg tablets/capsules or 16 individually wrapped sachets for pharmacy-only preparations.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

We believe this option is appropriate for the general population/those treating acute pain. However, for people using paracetamol to manage chronic pain, 32 tablets would not last very long.

Option 3

Option 3A - Allow only one pack to be purchased at a time without a prescription in pharmacies and for general sale.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

People with chronic pain conditions are often already financially disadvantaged due to the ongoing costs of medication, health appointments, reduced income opportunities and so on. If they required prescriptions to access paracetamol in bulk, it may end up costing them more for a medication that is an essential part of their treatment.

For example:

- The rough cost of a pharmacy-brand pack of 100 x 500mg paracetamol tablets is around \$3/pack. Yet, the cost of a prescription medication at concession rate is currently \$6.80. To make this cost comparable, each dispensed script would need to include at least two packs.
- The cost of seeing a doctor to get a prescription adds to the financial burden and would be prohibitive for some people, especially if they don't see a doctor regularly. Getting to a doctor can also be challenging due to waiting times for appointments, mobility issues, travel costs and the amount of physical and mental energy needed to get there (not to mention potentially increased pain levels from the physical effort).

Therefore, we believe bulk buying should continue to be allowed.

A compromise could be having a two-pack limit for general sale and multiple packs available OTC at pharmacies. We know that supermarkets and other general retailers managed to have purchase limits on other products (such as toilet paper and hand sanitiser) during the COVID-19 pandemic lockdowns so it could be done again. However, we also note this can be difficult for staff to monitor and may put them in stressful situations with unhappy customers.

Option 3B - Allow only one pack to be purchased at a time without a prescription in preparations for general sale.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

As per our previous comment, we believe it is feasible to impose pack limits for general sale of paracetamol products. Consideration would need to be given to the pack quantities and the dose per unit (500mg or MR 665mg).

Option 4

Option 4 - Prevent display and self-selection of paracetamol from non-pharmacy outlets - i.e. require paracetamol to be purchased from behind the counter.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

We do not believe this is a fair or practical solution. People taking pain medications regularly already face social stigma and they may be self-conscious about having to ask a staff member for them, especially if the staff member has had no training in selling medical products.

Having to ask for paracetamol products may also create an accessibility challenge for some people, such as those with language or social barriers.

Additionally, having all paracetamol products OTC only could place undue pressure on staff and require a redesign of store shelving and counters (as occurred with cigarettes and related products).

Option 5

Option 5A - Restrict minimum age of purchase to those 18 years and over in pharmacies and for general sale.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

While we understand the research accessed for the report showed teenagers are more at risk of harm from paracetamol dose than other age groups, we do not believe the low rates of this as a proportion of the population justify posing this age restriction.

People under 18 also have the right to access paracetamol products to manage their pain appropriately and we believe this restriction could be a form of discrimination. Many older teens already manage some or all their health issues independently. For example, girls with menstrual pain or any teen with autoimmune conditions such as arthritis should be able to go to a supermarket and buy a pack of paracetamol without hindrance.

We don't see how this could be managed appropriately in retail settings in any case. Most people under 18 don't have an accepted form of ID so this would place undue pressure on staff and may lead to embarrassing situations or altercations.

We agree that paracetamol products should not be sold directly to children or adolescents in any context, but we don't see how this could be policed.

Having made these points, we believe teenagers would benefit from seeing a GP to help them monitor their condition and potentially find other non-medical pain relief options or more appropriate medications. GPs may also be able to identify teens with increased risk of related health issues such as kidney or liver damage. Therefore, it would be worth considering allowing teens with recurring or chronic pain to access paracetamol products in bulk via prescription with or without parental approval.

Option 5B - Restrict minimum age of purchase to those 18 years and over in preparations for general sale.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

As above

Option 6

Option 6 - All modified release paracetamol should be rescheduled from Schedule 3 to Schedule 4 (prescription only), without change to maximum pack size.

(Required) **Support** **Partially support** **Do not support** **No comment**

Our comments

While we acknowledge this may help minimise people using MR products for acute pain, it may also impose cost and accessibility barriers for those who use it daily for chronic pain.

Those taking the maximum of six tablets/day need around 180 tablets/month or just under two packs. Currently, the average retail price of a pack of 96 x MR release paracetamol (665mg) is \$12 but it is often available on sale for \$9+.

Given that the current PBS script price is around \$14 non-concession and \$6.80 concession, the cost/pack is generally cheaper via prescription than over the counter. However, the cost and inconvenience of seeing a doctor to get a prescription still makes this option more expensive overall. (See our comments about the cost of seeing a doctor in our response to Option 3A.) Therefore, we believe prescriptions would need to include at least four packs and/or larger pack sizes to help offset the cost of a visit to the doctor.

Our response to non-medication specific recommendations to reduce self-poisoning

Recommendation 5: Use safe reporting guidelines for any communication around the harms associated with paracetamol overdose.

We believe it is important for people with chronic pain to have regular conversations with their treating doctors about the risks and benefits of all their medications, even if they have been on them for years.

Pharmacists can also help to reduce the likelihood of harm associated with paracetamol (and other medications) by using printed literature to promote the [Home Medicines Review](#) scheme in-store and discussing it with their customers as appropriate.

We believe strong consideration should also be given to adding more prominent warnings about potential risks on product packaging and store displays. For example, these could include the point that taking more tablets won't improve pain relief.

Recommendation 6: Maintain and expand support for aftercare services.

We agree with this recommendation.

Recommendation 7: Safer storage of medicines and reduced stockpiling of unwanted medicines

We agree this is an important area to pursue and, again, add that the Home Medicines Review scheme is an effective resource that could be better utilised.

Additional comments from our community members

“As someone with chronic pain due to a genetic disorder, I rely on paracetamol being available to buy readily and cheaply from the supermarket.

I cannot afford the costs involved with buying more prescriptions. I cannot afford the energy involved in getting more prescriptions from the GP. I simply do not have this energy to spare.

Please do not make pain relief any harder than it already is in Australia for people with chronic pain.”

Bridie McLean

“My husband has advanced osteoarthritis and can only take paracetamol MR for pain relief due to chronic kidney failure (from tumours and surgery).

He takes 2 x 3 times a day so a 96 pack only lasts 2 weeks approx. If he needed to get it by script only it would cost \$80 for the doctor’s visit plus the extra cost if the packaging size is reduced.

Restricting the number of packages per purchase means more trips to the pharmacy so (there will be) extra cost also in the petrol to drive there as well as the energy needed for parking and walking to the pharmacy.

We are both elderly - more frequent visits to the pharmacy increases the chance of catching viruses etc from others.

Restricting paracetamol to over 18s would work as parents could monitor the number of purchases as they would be doing the buying.

These are the issues that would severely affect our lives. He also has terminal CA.”

Rodney and Jill Sloman

“By all means, take it out of supermarkets. But leave it prescription-free, over the counter and 18+ at the chemist.

All chemists are computerised these days, surely it wouldn't be hard to maintain a database that is accessible to all chemists to prevent store crawling for those who are so inclined.

We use MR paracetamol. I really do not want to see this become prescription only. It's too hard to even get in to see a doctor these days, they are becoming very rare beasts!”

Chris Higgs

“Pack limits and restrictions on paracetamol will have a significant and devastating impact on the chronic pain community. As someone living with fibromyalgia and adenomyosis, paracetamol is my first line of medication in addressing my crippling chronic pain that is often so bad, I can’t walk or move.

Requiring us to get prescriptions is ableist and time-consuming. It's not always accessible to visit your doctor, especially with telehealth being reduced. It can be costly, as well as exhausting, particularly for those of us living with chronic fatigue. Sometimes, I'm exhausted just walking to my living room, so forcing me to attend another medical appointment will have a significant impact on my quality of life, as well as thousands of other Australians.

Furthermore, restricting the sale of paracetamol to people over 18 will be extremely detrimental to young people living with pain. They deserve access to medication as well, without needing to jump through extra exhausting hoops. I would especially like to point out that conditions that affect people with uteruses, like endometriosis and adenomyosis, can begin from a young age. For me, it was from age 12 with my first period. And that pain was so bad, I often couldn't walk. In fact, it's worse than a broken bone.

Many chronic pain sufferers don't have access to stronger pain relief, so paracetamol and ibuprofen are all they have. Please don't make it even harder.

Please consider the disabled community in these impacts. The medical industry is already hard enough to navigate, and many of us already have multiple appointments a week, and sometimes, multiple appointments a day."

Zoe Simmons

"I agree with the age restrictions and that it should only be sold in a pharmacy but to make the packages smaller won't change anything, people will just go from one pharmacy to another to get as many as they want.

I do not agree with making them prescription-only medication, it is hard enough getting the scripts I need now without that and the costs of doctors' appointments are going up all the time. I don't receive any help from the government so it would make it more expensive not only for a script but to have it filled as well, more handling by pharmacists will mean higher costs. As it is extremely rare when considering the amount of paracetamol sold in Australia daily, I think this is an unnecessary step.

I think there needs to be something in place for people who need this medication on a daily basis, it is getting harder and harder for people suffering with chronic illnesses to get the medication we need and this will only make it harder and more expensive. It's not fair that we should be penalised for others making poor decisions."

Marian Main

"I don't mind getting a script for Panadol Osteo as I have to get other scripts anyway. A pack of 96 costs around \$12 when not on sale. I usually buy 2 packs at a time and use 2 tablets x 3 a day. That's almost 2 packs a month = roughly \$24.

If I buy them on prescription, I may get multiple boxes per script. Each script costs \$6.80 if you have a concession card. Then, once you hit the safety net, scripts are free for the rest of the year, so I'll save money getting it that way."

Steve Ainley

Samples of social media comments

"It cost me \$95 to get two prescriptions and one referral on telehealth."

Marilyn, Facebook

"We autoimmune sufferers often need this simple, OTC medication as a baseline pain reliever. It doesn't do much, to be honest, but assists somewhat, especially with inflammation, aches, pains etc. Surely, the general population are educated well enough these days to know how to take this medicine that's been around for years."

Lesley, Facebook

"I work as a nurse and previously worked in Emergency where I saw quite a few paracetamol overdoses, unfortunately. I think some people do see this as an OTC drug and therefore don't think it has any medical consequences if you take more than the packet states."

Nikki, Facebook

"I come from the UK where these restrictions are already in place and have been for some time. When I moved over here 7 years ago, I was shocked by the availability of paracetamol/slow-release medication. I hope that they can achieve a compromise to accommodate the needs of people with chronic pain versus the need to reduce the risks associated with suicide."

Susan, Facebook

"It's all you get in hospital. Two tablets every six hours. Wonder what other suggestions they have for aches and pains?"

Jeanette, Facebook

"I think there needs to be more information put out re the harm that paracetamol can potentially cause."

Niki, Facebook