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Submission on proposed amendments to the Poisons Standard in relation to paracetamol – Therapeutic Goods Administration, ACMS meeting, November 2022

ABOUT US

Arthritis Australia is the peak arthritis organisation in Australia and is supported by affiliate organisations in ACT, New South Wales, Northern Territory, Queensland, South Australia, Tasmania and Western Australia.

Arthritis Australia provides support and information to people with arthritis as well as their family and friends. It promotes awareness of the challenges facing people with arthritis across the community, and advocates on behalf of consumers to leaders in business, industry and government.

In addition, Arthritis Australia funds research into potential causes and possible cures as well as better ways to live with the disease.

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Introduction

Thank you for the opportunity to provide input to the TGA consultation on proposals to restrict access to paracetamol.

We understand that the intent of the proposed regulatory changes is to reduce harms and deaths related to paracetamol poisioning and particularly intentional overdose, and we strongly support this intent. We note the TGA's acknowledgement that "any additional restrictions needs to be balanced with whether there would be a broader impact on consumer access", but that the scope of the *Independent expert report on the risks of intentional self-poisoning with paracetamol* that underpins the proposed changes is limited to "the benefits and risks of the current access to paracetamol on the Australian market in relation to intentional self-poisoning" and does not consider broader impacts on other users such as people with arthritis related chronic or episodic pain. We urge a broader consideration of the benefits and risks and potential unintended consequences of the proposed changes for paracetamol users with arthritis pain, particularly given consumer's experience of previous reforms.

There is very significant unmet need for access to safe and effective care and treatment of arthritis, and specifically pain management in Australia. There is a need for continued support to implement the National Strategic Action Plan for Arthritis, in particular increasing access to high value, person centred care.

While there was a clear need to reduce harms associated with opioids and inappropriate prescribing, regulatory changes were rolled out with inadequate support or access to alternatives. This has caused very real distress for consumers who relied on such medicines as prescribed by their doctor long term to manage their pain. As documented in Painaustralia's August 2020 survey, consumers felt abandoned and stigmatised, lost function and autonomy, and there were significant mental health impacts[1]. It is critical that in the rollout of such changes, appropriate information, education and support is provided to consumers and health professionals, and we would urge that any reviews of the outcomes of such reforms include consideration of unintended impacts and how such rollouts can be done better in future.

We strongly support the Independent Expert Report's non-medication specific recommendations to reduce self-poisoning and urge that these be implemented. We also strongly support some of the proposed measures in this consultation, such as the prohibition of display of paracetamol, and age restrictions.

However, we are concerned that consumers who still face access and cost barriers for care and treatment of their arthritis and a lack of alternatives for pain management, and wish to continue responsible use of paracetamol with the support of their treating health professionals, will be negatively impacted by some of the proposed changes. These impacts would likely include increased out of pocket costs, from likely pricing increases due to pack size reductions, and the requirement for more GP attendances, and barriers to access if they are able to purchase less of their supply and are forced to make additional trips to the pharmacy or other outlets – for people living with significant pain and disability, these are not trivial issues. Consumers we have consulted have also expressed a sense of fearfulness and disempowerment that their few options for managing their pain are being whittled away without any support being provided.

As the TGA has acknowledged, the harms of a potential increase in usage of NSAIDs long term as a consequence of paracetamol being less available also need to be considered.

We would like to see regulatory reforms such as these integrated into a broader policy approach that considers and addresses unmet healthcare needs. Any review of the impacts of the proposed reforms should include consideration of these broader issues. If there is increased support for people with arthritis-related pain to access effective alternatives to manage their pain, consumers may be more supportive of further regulaton of paracetamol in future.

Issues for people living with arthritis

Arthritis is one of the most common, costly and disabling chronic conditions in Australia, with at least one in seven Australians (over 3.6 million people) living with arthritis. There are over 100 types of arthritis, with the most common types being osteoarthritis (a degenerative disease affecting joints) and rheumatoid arthritis, an autoimmune disease.

Over 60% of people with arthritis have chronic pain[2]. People with arthritis often report that their health care professionals, including specialists, do not understand the impact that arthritis can have on their daily lives, especially pain and fatigue[3].

Effective pain management is one of the highest priorities reported by people with arthritis. Poorly controlled pain in inflammatory arthritis is associated with lower quality of life and higher levels of disability, emotional distress and depression[4]. There is evidence to support a variety of pharmacological and non-pharmacological treatment options for pain management, especially physical activity and exercise and psychological interventions[5]. However, pain is most commonly treated with medication.

Paracetamol is commonly used by people with arthritis, especially osteoarthritis, to manage pain, and paracetamol has until recently been recommended as a first-line therapy for osteoarthritis. However, there is increasing evidence that paracetamol may be of limited clinical benefit in the management of this condition[6] and that adverse effects may be more common than originally recognised,[7] although adverse effects occur less frequently than with NSAIDs and opioids. The RACGP Guideline for the management of knee and hip osteoarthritis now recommends exercise and weight loss as first line therapies for this condition. The Guideline does not recommend either for or against paracetamol, but suggests it may be reasonable to trial paracetamol for a short period in some people with knee and/or hip OA, with monitoring of possible adverse effects, then discontinue use if not effective.

Strategies such as weight loss and strengthening exercise have benefits comparable to medication[8] but with few side-effects for people with osteoarthritis and may also delay disease progression. However these interventions currently receive little support through the health system, limiting their uptake.

Based on the current evidence, we do not wish to perpetuate the use of paracetamol as a part of best practice care. However, we recognise that many consumers with arthritis have relied on long term regular paracetamol use and their experience is that it helps them manage their symptoms and allows them to undertake their daily activities. It is imperative that people with arthritis-related pain are provided with more support to access evidence based and effective alternatives, including through the Medicare Benefits Schedule. For some people this will require access to

multidisciplinary pain management, while others will need more targeted plans to manage episodic pain.

The TGA has acknowledged in its pre meeting public notice that there are risks associated with long term use of alternative over the counter pain medicines, and that "if access to paracetamol is restricted there may a flow-on increase in usage of ibuprofen in particular… In this case it will be important to emphasise that alternatives such as OTC non-steroidal anti-inflammatory medicines, such as ibuprofen, are only recommended for short-term use as they can cause adverse effects, such as intestinal bleeding, cardiac disorders, kidney and heart failure, or liver damage. In addition, some people are also allergic to ibuprofen and aspirin. Aspirin can cause gastro-intestinal irritations and is contraindicated in those with bleeding disorders."

Out of pocket costs are also a major issue for people with arthritis. Consumers in Arthritis Australia's 2018 survey reported that they faced extremely high cumulative costs associated with managing their condition, and relevantly the cost of medicines, and of allied health services mostly accessed privately, were a concern.

In our submission in relation to the 2018 proposal to up-schedule modified release (MR) paracetamol to a 'pharmacist only' medicine, Arthritis Australia supported this in principle, acknowledging the need to address the particular risks associated with overdose. However, during our consultation on our submission consumers expressed concern regarding the cost impact, as the up-scheduling would make it less likely the product would be discounted. We also noted that the cost of MR paracetamol is a particular concern for people with arthritis following the delisting of paracetamol from the PBS in 2016, and recommended that pricing of the MR formulation be monitored following upscheduling to ensure that it remains affordable for those who need it. We did not support reduced pack sizes due to the likelihood that this would increase the cost of the product to consumers.

Table 1 below contains our responses to the detail of each proposed change in the current consultation.

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Proposed change	Options	Arthritis Australia response
1. ***Requirement for blister packs***. It is slower to consume paracetamol tablets or capsules that must be individually ejected from blister or strip packs as compared to other packaging (e.g. bottles). Slowing the consumption of multiple tablets or capsules by restricting these dosage forms to being presented in blister or strip packs may reduce the likelihood of overdose and harm from impulsive attempts to self-poison.	**Options 1A-C: Blister packs** *Description* Solid dose paracetamol (tablets/capsules) made available only in blister packs (not loose dose units): Option 1A: for general sale preparations only (amendment to Schedule 2 entry, paragraph g); Option 1B: for general sale and pharmacy preparations only (amendment to Schedule 2 entry, paragraphs c) and g)); Option 1C: for pharmacist only, pharmacy and general sale preparations (amendment to Schedule 3 entry, paragraph b) and Schedule 2 entry, paragraphs c) and g)). Option 1D: for prescription only, pharmacist only, pharmacy and general sale preparations (amendment to Appendix D, Schedule 3 entry, paragraph b), and Schedule 2 entry, paragraphs c) and g))	We note that this was not a recommendation of the Independent Expert Report. It is important to understand that people with arthritis may have difficulty and pain opening packaging. Our consumers have also expressed some concern about the environmental impacts of an increase in packaging for such a commonly used medication. While we would support blister packs being implemented for general sale and pharmacy preparations, we believe that loose dose units should continue to be available for pharmacist only and prescription preparations. In cases where blister packs are used, manufacturers should be encouraged to apply accessible design principles and user testing. Arthritis Australia's Accessible Design Division has a range of resources and guidance for industry -

		https://arthritisaustralia.com.au/accessible-design-division/resources-for-industry/
2. 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 32. This would reduce the number of grams of paracetamol held in homes and thus the numbers of very large overdoses taken in impulsive self-poisonings.	**Options 2A-B: Pack size** *Description* Reductions in the maximum paracetamol pack size sold in Australian retailers: Option 2A: for general sale preparations, to be reduced to 10 x 500 mg tablets/capsules or 5 individually wrapped sachets (amendment to Schedule 2 entry, paragraphs g) (ii)(A) and (iii)(B)); Option 2B: for pharmacy only medicines, to be reduced to 32 x 500 mg tablets/capsules or 16 individually wrapped sachets (amendments to Schedule 2 entry, paragraphs f) and g) and Schedule 2 entry, paragraphs c), g)(ii)(A) and (iii)(B)).	Reductions in pack sizes is likely to increase cost. Out of pocket costs are a major issue for people with arthritis, as set out above. We would support pack size reductions for general sale, but larger packs should be available from pharmacies, possibly behind the counter or with an age limit. Following any changes, pricing should be monitored and measures taken to ensure paracetamol remains affordable for long term use.
3. 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 reduce home stockpiles, and likely also reduce the number of very	**Options 3A-B: Restrictions on the purchasing of multiple packs** *Description* Allowing only one pack to be purchased at a time when purchased in the following retail settings: • Option 3A: without a prescription in pharmacies	This is likely to impact people with chronic arthritis pain and disability, as it will require them to make more trips to the shops or pharmacy to purchase paracetamol. We recommend that people who are on regular paracetamol should be able to purchase a month's supply at a time.

large overdoses, which have much higher morbidity and risk of death.	(amendment to Schedule 2 entry paragraphs c) and e)), or • Option 3B: in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)).	It should also be recognised that people particularly in rural or regional areas may have more limited access to a pharmacy and opening hours may be more restricted than for other retail outlets, meaning option 3B may disproportionately impact them.
4. ***Sale from behind the counter***. The prohibition of display and self-selection of paracetamol in general (non-pharmacy) retail outlets may discourage impulsive purchasing by those vulnerable to overdosing with paracetamol.	N/A	We strongly support this proposal, and suggest that it is extended to pharmacies. Anecdotally consumers have reported very large discounted displays of paracetamol at pharmacies which we would expect pose the same risk to vulnerable people as those in other retail outlets.
5. ***Modified Release paracetamol restrictions.*** This product is designed for long-term use (e.g., for osteoarthritis), rather than for acute pain. Prescription only (S4) scheduling would be expected to reduce inappropriate use of this product which is harder to treat in overdose than immediate release paracetamol.	N/A	The MR formulation is commonly used because it requires less frequent dosing, making it more convenient to use for chronic pain. We recognise that MR preparations are a particular concern in relation to paracetamol poisoning, and that the Independent Expert Report advises that the upschedule to S3 has not made an impact and recommends that upscheduling MR to prescription-only is likely to have the largest impact in reducing overdose harms. While making this prescription-only may adversely affect cost and access for people with

		chronic pain, on the basis on the expert advice we support this change.
6. ***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.	N/A	We are supportive of this measure.

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Recommendations

We strongly support the Independent Expert Report's non-medication specific recommendations to reduce self-poisoning and urge that these be implemented:

1. **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.
2. **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.
3. **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.

We also strongly recommend that the effects of any changes on usage of NSAIDs and aspirin by people with chronic pain be actively monitored.

In relation to the broader issue of inadequate access to arthritis care and treatment, and pain management in Australia, we recommend:

- Reconvening key stakeholders to review progress in implementing the National Strategic Action Plan for Arthritis and the National Strategic Plan for Pain Management, and provide further funding to fully implement the Plans.
- Improving access to effective treatment and management of arthritis as a leading cause of pain, as well as chronic pain itself, including improving affordable access to interdisciplinary team care:
    - Develop, trial and implement funding models (public and private) to better support appropriate team-based care for people with arthritis. Funding models should enhance affordable access to evidence-based interdisciplinary packages of care including patient education and support, exercise, healthy diet advice, weight loss, pain management and psychological health interventions, tailored to an individual's needs and preferences.
    - Increasing the number of allied health services available under MBS Chronic Disease Management items. Based on the clinical judgement of the treating clinician, people with arthritis who may benefit should be able to receive an additional five services per calendar year.
    - Providing MBS funding for group allied health services, including assessment and review, for people with arthritis (as is currently available for people with type 2 diabetes).

    - Develop pathways and recognition processes for advanced practice nurses and allied health professionals with particular expertise and experience in managing complex patients with arthritis. This would assist health professionals and people with arthritis to identify appropriately-skilled practitioners in their local community.
    - Ensure affordable access to other relevant physicians and specialists, such as pain specialists, sports and exercise physicians, orthopaedic surgeons and rehabilitation physicians, as part of the interdisciplinary team, in line with an individual's needs.
- Increase the uptake of effective lifestyle and self-management interventions for people with arthritis:
    - Support health and non-health professionals with training and tools to recommend and deliver tailored, evidence-based, non-pharmacological and non-surgical care and support for people with arthritis
    - Provide funding for people with arthritis to access arthritis-appropriate evidence-informed exercise programs, pain coping skills training and weight loss services.
    - Upskill and accredit exercise professionals in the delivery of evidence-based, arthritis appropriate exercise programs
    - Increase affordable access to exercise health professionals, such as specialist sport and exercise physicians, physiotherapists and exercise physiologists, to enhance exercise therapy for people with arthritis.
- Increased awareness and access to information on effective pain self-management strategies for consumers, including Arthritis Australia information resources such as MyJointPain and MyRA.
- Increased access to non-pharmacological approaches to pain management, including better access to affordable, appropriate multidisciplinary care for management of more complex chronic pain:
    -
    - Fund MBS item for pain education by medical, nursing or allied health practitioners, like the diabetes educator model which is already funded under the MBS.
    - Fund MBS item for GPs with specialist qualification in pain medicine as a fellow of the FPM.
    - Provide an MBS item for chronic pain group programs that are similar to those provided for mental health.
- Increased education and training in effective pain management strategies for health care practitioners.
- Provide consumers with access to effective resources that enable them to communicate and navigate their pain experience between health providers, workplaces, carers or family to reduce stigma, the need to repeat their story and better self-manage pain.
- Increased investment in research into effective arthritis treatment and pain management, including safer and more effective pharmacological management options.

Conclusion

Arthritis Australia thanks the TGA for the opportunity to make this submission, and trusts that the issues raised with regard to impacts on people with arthritis will be fully considered, and lessons learnt from the rollout of the opioid regulations. We also intend to raise these issues, and our

broader recommendations around access to arthritis care and treatment and pain management, with the Minister for Health and Aged Care.

[1] Survey report: impact of 2020 opioid reforms on people living with chronic pain. August 2020, Painaustralia.
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[7] Roberts E et al 2015 Paracetamol: not as safe as we thought? A systematic review of observational studies. Ann Rheum Dis doi10.1136/annrheumdis-2014-206914
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