31 October 2018

Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Thank you for the opportunity to provide input to the TGA consultation on the proposal to up-schedule modified release (MR) paracetamol to a 'pharmacist only' medicine.

Arthritis Australia is the peak national organisation representing people with arthritis in Australia. This consultation is of interest to us because MR paracetamol is commonly used by people with arthritis, especially osteoarthritis, to manage persistent pain associated with their condition.

The role of paracetamol in arthritis management

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[1] and that adverse effects may be more common than originally recognised,[2] although adverse effects occur less frequently than with NSAIDs and opioids.

The most recent 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[3] 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.

Nevertheless, many people with various forms of arthritis rely on paracetamol for pain relief and the MR formulation is commonly used because it requires less frequent dosing, making it more convenient to use for chronic pain. Many consumers also report that paracetamol takes the edge off their pain so that they can exercise, which in itself is an important pain management strategy.

Proposed rescheduling

Arthritis Australia acknowledges the need to address the particular risks associated with overdose related to the MR formulation of paracetamol due to its unpredictable pharmacokinetic profile.

For this reason we support in principle the proposed rescheduling of slow release paracetamol from Schedule 2 to Schedule 3 as a means of reducing the risk of either accidental or intentional overdose. The re-scheduling will provide the opportunity for pharmacists to advise people of the importance of not exceeding the correct dosage, while retaining over-the-counter access to these products.

However, we note that some consumers consulted in the preparation of this submission have expressed concern regarding the cost impact of the up-scheduling, as this reduces the likelihood of discounts being offered on the product. The cost of MR paracetamol is a particular concern for people with arthritis following the delisting of paracetamol from the PBS in 2016. We recommend that pricing of the MR formulation be monitored following up-scheduling to ensure that it remains affordable for those who need it.

We also note that the MR formulation is associated with less than 10% of paracetamol-related overdose in Australia,[4] so the issues associated with the MR formulation are part of a much wider problem. Consequently we suggest that a consumer education campaign is required to support safe usage of paracetamol of any formulation. This should be supported by clearer labelling and warnings relating to the potential safety risks associated with paracetamol, including overdose.

Arthritis Australia would not support reduced pack sizes for MR paracetamol as this is likely to increase the cost of the product to consumers, the bulk of whom continue to use this product in accordance with recommended dosage.

Improving arthritis management

Arthritis Australia is currently developing a National Strategic Action Plan for Arthritis for the Department of Health. This Action Plan will include a number of recommendations for improving arthritis management including increasing access to exercise, weight loss and other non-pharmacological pain management strategies. These approaches have been shown to be as effective as medication for managing osteoarthritis, but without the same risk of adverse events. Better health system support for these strategies offers significant potential to reduce reliance on pharmacological treatment, including paracetamol, for osteoarthritis s management.

For further information, contact Franca Marine at fmarine@arthritisaustralia.com.au

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[1] Machado C et al 2015 Efficacy and safety of paracetamol for spinal pain and osteoarthritis: systematic review and meta-analysis of randomised placebo controlled trials. BMJ 2015; 350:h1225

[2] 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

[3] Fransen M, McConnell S. Exercise for osteoarthritis of the knee. *Cochrane Database of Systematic Reviews* 2008; Issue 4. Article no CD004376. DOI: 10.1002/14651858. CD004376.pub2.

[4] Chiew AL, Isbister GK et al (2018) Modified release paracetamol overdose: a prospective observational study (ATOM-3) Clinical Toxicology, DOI: 10:1080/15563650.2018.1439950