TGA MODIFIED PARACETAMOL CONSULTATION SUBMISSION FROM PAINAUSTRALIA

October 2018

About Painaustralia

Painaustralia is the national peak 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. Members include pain and other specialists, health practitioners, health groups, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue.

Executive Summary

Painaustralia welcomes the opportunity to provide input to the Therapeutic Goods Administration's (TGA) consultation on the proposed amendment to the current Poisons Standard to the meeting of the Advisory Committee on Medicines Scheduling (ACMS).

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Painaustralia and its members have been actively engaged on the issue of quality use of medicines for many years. As the TGA's consultation paper notes, MR paracetamol is a widely used medicine in Australia and overall paracetamol related overdose remains common. Our submission is based on input provided to our survey on MR paracetamol, consultation with our founding members, the Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine (FPM) and the Australian Pain Society (APS) as well as other members and stakeholder groups like Arthritis Australia and the Consumers Health Forum of Australia.

As many people living with chronic pain opt to self-medicate their condition, it is vital that they are able to understand the components of their medication, and the risks associated with them. When it comes to commonly used medications that are available over the counter, clear visibility of safety concerns is vital to ensure consumers are aware of the risks and in aiding consumers to comply with their treatment and avoid adverse health outcomes.

To summarise the use of MR paracetamol, as detailed by the Department of Health Application include:

1. Unpredictable and undefined pharmacokinetic profile
2. Severe consequences of overdose may be more likely to occur in patients who have ingested MR paracetamol
    a. High potential for treating clinician to not be aware that a patient has ingested MR paracetamol
    b. Unpredictable pharmacokinetic profile making monitoring and treatment difficult
3. Current best practice guidelines do not completely address MR toxicity
4. Large standard pack size facilitates consumption of higher dose

As summarised in the application, MR paracetamol would appear to provide little benefit over standard IR paracetamol other than less frequent dosing.

Overall, Painaustralia and our members are supportive of the rescheduling of slow release (MR) paracetamol, from Schedule 2 to Schedule 3, and the correction of terminology from slow release to modified release to accurately reflect the formulation of these products. In implementing these changes, Painaustralia also recommends further education and awareness around paracetamol products, to ensure that consumers are vigilant to the risks posed by these medications. The impact upscheduling has on the cost of MR paracetamol, as well as any additional barriers consumers face in accessing appropriate pain management should be evaluated as a part of the TGA's proposed change processes.

Painaustralia recommends:

1. **The upscheduling of MR paracetamol from Schedule 2 to Schedule 3.**
2. **The upscheduling be supported by targeted consumer education around quality use of paracetamol.**
3. **Upscheduling be evaluated in 12 months to assess the impact on consumer access.**
4. **The National Streatgic Action Plan on Pain management be implemented to ensure that consumers and health professionals have a better understanding of pain management and that the training, education and supports and services are in place to support these regulatory changes.**

Understanding Pain

One in five Australian adults are estimated to live with chronic pain (daily pain for more than three months, experienced in the last three months).[1] This is consistent with global estimates.[2] Pain in general is prevalent, with 67% of Australians reporting experienced bodily pain in the last four weeks in 2007-08. Around one in ten Australians experience severe or very severe levels of pain.[3]

The rates of chronic pain are on a par with the prevalence of mental health in Australia,[4] yet pain remains a neglected and misunderstood as a public health issue.[5] 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.[7] 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.[8] This may be due to a greater proportion of the working population undertaking manual labour in these communities, increasing the incidence of workplace injury which can lead to pain conditions.

Children and adolescents are also affected by chronic pain, though it can be overlooked in these age groups due to a range of factors. Between 25 to 35 per cent of children experience chronic pain, with the greatest incidence in adolescents, especially for young girls, and about five per cent of children have moderate to severe pain, with headaches, abdominal pain, limb pain and complex regional pain syndrome the most common forms of pain.[9]

Upscheduling MR Paracetamol

As noted in the Department of Health's application to amend the Poisons Standards,[10] there are 26 MR paracetamol products currently entered on the Australian Register of Therapeutic Goods (ARTG). It is currently a Schedule 2 (Pharmacy Medicine), and available over the counter at any pharmacy.

The only real benefit MR paracetamol offers in comparison with Immediate Release (IR) paracetamol appears to be less frequent dosing and therefore may be more convenient for longer term use in patients with chronic pain conditions such as osteoarthritis. It's easy accessibility over the counter (OTC) also means consumers do not need to visit their doctor in order to obtain a prescription.

MR paracetamol is thought to be widely used in Australia to manage chronic pain in the elderly, but as it is an OTC product, it is difficult to estimate the volume of usage. However, overdose with paracetamol (immediate and modified release) whether intentional or accidental, is common in Australia and in many other countries.

Overdose with MR paracetamol poses risks over and above that of IR paracetamol due to its unpredictable pharmacokinetic profile, the consequences of which can be severe.

"I think the general public aren't aware of the potential danger of "basic" medications such as paracetamol and ibuprofen. I strongly believe that the issue with over the counter codeine was from people overdosing on the paracetamol or ibuprofen part. My grandfather died partly of paracetamol overdose so it is a cause close to my heart. People need to understand the dangers. I hear of people taking 3 panadeine forte tablets at once because they "need the pain relief", but they don't realise they are doing so much damage to their bodies. Elderly people also need to be aware!"
Response to Painaustralia survey on MR Paracetamol

In addition, contemporary research now challenges paracetamol and its effectiveness and safety in patients longer term (musculoskeletal) pain conditions. A systematic review of trials of paracetamol as an analgesic has shown it is no more effective than placebo for low back pain and has a small effect for osteoarthritis.[11]

We support and endorse the TGA's proposal of upscheduling MR paracetamol to an S3 medication. While Painaustralia and our members agree in principle with improving safety and the proposed up-scheduling, it is important to ensure further steps are taken to inform consumers more clearly about the risks associated with MR paracetamol.

Need for consumer education and awareness

The reasons for overdose with MR paracetamol products in Australia are difficult to ascertain from the adverse event data currently available. The adverse outcome reports seem to largely relate to intentional or polypharmacy overdose which is unlikely to be altered by a change in scheduling alone.

The main issue to address should include an emphasis on educating consumers on the quality use of all paracetamol, IR and MR. Upscheduling is unlikely to accomplish the reduction in adverse events when access if consumers remain unaware of the potential risks of posed by MR paracetamol.

"Information about safe doses for paracetamol needs to be provided far more clearly, ie on packets, advertising and by health professionals. Most patients are not aware of dose limits and consequences".
Response to Painaustralia survey on MR Paracetamol

"As a future pharmacist (current second year pharmacy student) it will allow for better counselling and decrease risk of accidental overdose due to taking multiple paracetamol containing products (many people still don't realise there is paracetamol in cold and flu or Lemsip preparations)"
Response to Painaustralia survey on MR Paracetamol

Painaustralia and our members therefore recommend that the upscheduling of MR paracetamol be accompanied by a targeted education and awareness campaign.around quality use of paracetamol.

Ensuring access to appropriate pain management

As noted in the Department of Health Application, MR paracetamol was previously available as a general listing on the Pharmaceutical Benefits Scheme (PBS) for the indication of osteoarthritis pain, but this has been restricted to palliative care and Aboriginal and Torres Strait Islander patients since January 2016. While the removal from the PBS has not impacted the price and availability of MR paracetamol significantly, we must monitor any potential impact on pricing following the upscheduling as well.

MR paracetamol is a cost effective and convenient way to access to pain management for longer term use in patients with chronic pain conditions such as osteoarthritis. Its easy accessibility OTC means consumers do not need to visit their doctor in order to obtain a prescription. In upscheduling MR paracetamol, we need to be cautious about creating additional unintended barriers to pain management for consumers.

Most people with osteoarthritis in Australia do not receive appropriate care. Current care is mostly palliative, with a focus on advanced disease, medication and surgery. Typically, treatment is limited to the use of paracetamol, non-steroidal anti-inflammatory medication, or opioids, to reduce symptoms until the condition worsens, at which point the patient is referred for a joint replacement.[12]

Clearly, there is a need to ensure that millions of consumers with painful conditions like osteoarthritis have access to timely and appropriate pain management. While we consider regulatory changes to improve quality use of medications such as MR paracetamol and opioids, we must also consider the need for alternative pain management strategies for consumers.

Conclusion

Painaustralia agrees that up-scheduling to S3 will provide an opportunity for pharmacists to counsel patients on the importance of not exceeding a dose of 6 tablets per day and provide a barrier to the impulsive purchasing of MR paracetamol for the purposes of taking an overdose, whilst still preserving OTC access to these products.

Additional steps need to be taken to promote quality use of paracetamol given it's wide usage and easy accessibility. Targeted education and awareness campaigns are needed to aid in informed decision-making by consumers. We need to ensure better awareness and provide more effective support to people living with pain if we are to reduce adverse events related to pain medication in Australia.

The implementation of a National Action Plan, currently being led by Painaustralia, is also an important step towards raising awareness, and ensuring that consumers and health professionals have a better understanding of pain management and that the training, education and supports and services are in place to support these regulatory changes. This will become a key component to supporting better pain medication management and ensuring quality of life while limiting the escalating social and economic costs of unmanaged pain.

We trust that the matters raised in our submission will be useful in helping the TGA finalise proposed amendments to the Poisons standards and welcome the opportunity to discuss our submission with you further.

References

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