

Therapeutic Goods Administration

18 May 2020

Dear Sir/Madam

CONSULTATION: Proposed amendments to the Poisons Standard – Down-scheduling of Ibuprofen 400 mg

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) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS).

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. As such, the issue of down-scheduling of ibuprofen 400 mg to a Schedule 2 listing, as proposed through the amendment of the Poisons Standards, is important to our members and stakeholders.

Painaustralia and its members have been actively engaged on the issue of quality use of medicines for many years. Non-steroidal anti-inflammatory drugs (NSAIDs) are the most commonly used pharmacological agents worldwide to treat mild to moderate pain. Ibuprofen is one of the most commonly used NSAID.

Enabling self-management of chronic pain

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 in pharmacy as a Schedule 2, clear visibility of safety and quality use of medication information is vital to ensure consumers are aware of the risks and in aiding consumers to comply with their treatment and avoid adverse health outcomes.

As summarised in the application, Ibuprofen 400 mg is appropriate for inclusion in Schedule 2 as it has a superior risk-benefit profile to that of paracetamol, aspirin and diclofenac, as single agents, as well as paracetamol/ibuprofen combinations. Ibuprofen 400 mg is as effective as the combination analgesic and is a safer option as people are only exposed to one active ingredient that is as well tolerated as paracetamol and is safer than paracetamol in overdose situations.

With the upscheduling of Modified Release Paracetamol this year, as well as the broader reforms to opioids, consumers will face barriers in accessing affordable pain management strategies. Improving the availability of 400 mg ibuprofen by permitting self-selection as a Schedule 2 medicine will provide consumers with an effective and safe option to relieve strong pain.

However, consumers have also flagged concerns around the proposed down-scheduling:

“Most people who take Nurofen or ibuprofen are used to the dosage of “take 2” which works for the widely available 200mg tablets/capsules. If you make 400mg ibuprofen available without pharmacist advice people will still take 2 because that’s what they’re used to”
Response to Painaustralia post on proposed down-scheduling

This concern raises potential safety in usage issues, especially in the older people with chronic pain who commonly rely on the use of NSAIDs for pain management and may be more susceptible to overdose issues.

It is also important to note that medication alone is not helpful for the management of chronic pain and patients need to adopt other strategies. All medications have side-effects and many which can be harmful if used over the long-term. We need to monitor the impacts of changes to scheduling that considers societal costs of overuse of medications and a shift from lifestyle and holistic interventions to pharmaceutical interventions. In short, we need to weigh the costs versus the benefits.

Painaustralia therefore recommend that the down-scheduling be accompanied by a targeted education and awareness campaign around quality use of Ibuprofen, as well as an evaluation of the change. The impact of down-scheduling particularly on overall hospital presentations is also an important factor that must be monitored as a part of the TGA’s proposed change processes.

Conclusion

Overall, Painaustralia is supportive of the down scheduling of Ibuprofen 400 mg in smaller pack sizes (max 12 doses) from Schedule 3 to Schedule 2. In implementing these changes, Painaustralia also recommends further education and awareness around NSAID’s, to ensure that consumers are vigilant to the risks posed by these medications.

Additional steps need to be taken to promote quality use of ibuprofen given its 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 Strategic Action Plan for Pain Management](#), currently being considered by the Council of Australian Governments, 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.

Yours sincerely

Carol Bennett
Chief Executive Officer