

painaustralia

SUBMISSION TO DEPARTMENT OF HEALTH

**Scheduling Delegates' interim decision on Ibuprofen and invitation for
further comment**

MARCH 2018

Summary of Recommendations

- Painaustralia supports the interim decision of the delegate that the current Schedule 2 and Schedule 3 entries for ibuprofen remain appropriate.
- Painaustralia recommends the department ensures the continued adherence to high standards of labelling and information for consumer awareness.
- Painaustralia recommends a review of existing public awareness campaigns and resources about ibuprofen in consultation with consumers.
- That consumer awareness of best-practice pain management be supported.

About Painaustralia

Painaustralia is the leading national peak body to develop and inform national pain strategies and policies and was formed in 2011 to work with government, health professional and consumer stakeholders to facilitate implementation of the National Pain Strategy.

Painaustralia's primary mission is to improve the quality of life for people with pain and their families and minimise the burden of pain on individuals and the community. Effectively tackling pain – as a complex physical, psychological and environmental condition – is in the interest of every Australian.

With over 150 members and partners across a diverse range of stakeholders including consumers, medical specialists, pharmacists, academics, carers, pharmaceutical companies, allied health professionals and others with an interest in pain, Painaustralia consults our network widely to inform practical and strategic solutions to address this complex and widespread issue.

We have a vast consumer network. Painaustralia also provides essential sources of information for consumers, medical practitioners and researchers.

Support for the interim decision

Painaustralia supports the delegate's interim decision following consideration of advice from the Advisory Committee on Medicines Scheduling (ACMS) that the current Schedule 2 and Schedule 3 entries for ibuprofen remain appropriate, as published on 5 February 2018.

The recent review of ibuprofen responded to a general application to the ACMS to amend the schedule 2 and 3 entries for ibuprofen in the Poisons' Standard with the aim of restricting the sale of ibuprofen to pharmacies only.

Painaustralia believes this change in scheduling would have a significant impact on consumer choice and accessibility with limited evidence that consumers would receive any benefit.

In supporting the interim decision, Painaustralia has carefully considered the reasons provided by the delegate,¹ including:

- There are no new publicly available safety concerns associated with this medication, which the TGA found to be overall safe and effective for the temporary relief of pain and inflammation when used as per the label.² If there are additional or unpublished concerns with current forms of ibuprofen they should be made available to the public.
- There are considerable consumer benefits of retaining 24-hour availability of 24 pack sizes for acute pain, particularly in rural or remote areas or other communities that do not have access to pharmacies that are open after business hours.
- There is a low propensity for toxicity in overdose and current labelling meets the Required Advisory Statements for Medicine Labels (RASML) in relation to risks and complications of nonsteroidal anti-inflammatory drugs (NSAIDs).
- There is no evidence of excessive use, purchasing or harm through the continuation of Schedule 2 availability.
- The current Australian scheduling arrangements for ibuprofen are in line with other countries including the UK, Canada, The USA and New Zealand.

Painaustralia also notes that ibuprofen has been available in Australia as an over-the-counter (OTC) medication for 30 years, and in general retail for approximately 15 years, with limited reported adverse effects.

We also note that 17 submissions were provided to the initial consultation process on this review in January 2018, with 14 indicating they were opposed to rescheduling.

Painaustralia survey

The reasons outlined by the delegate for retaining current ibuprofen scheduling arrangements are supported by a recent online survey that was conducted by Painaustralia throughout February 2018. The survey was promoted through Painaustralia's network and provided the following insights:

- The survey received 108 responses. 100 of these identified as an individual consumer and the remaining responders indicated they were responding on behalf of an organisation.
- 69.9% of responses supported continued availability for sale in supermarkets and general retail outlets. Over 60% of responses believed short term pain relief, convenience and out of hours access were all important reasons to continue current arrangements.
- 80% of responses felt they had enough information on the benefits and risks of ibuprofen.
- While 37.27% of responses thought pharmacist, doctors, friends and family, information leaflets, public awareness campaigns and packet labelling all had a role in disseminating information about ibuprofen, 29.09% thought packet labelling alone to be the most important way to receive information.

Recommendations:

Painaustralia supports the interim decision of the delegate that the current Schedule 2 and Schedule 3 entries for ibuprofen remain appropriate.

Consumer information

Packet labelling

The Painaustralia survey highlighted the critical role of packet labelling to communicate the risks of all medications. 48.18% of responses thought changes need to be made to the way pain medications containing ibuprofen are labelled or packaged, which outnumbered those who did not (43.64%).

While noting current labelling meets RASML in relation to risks and complications of NSAIDs, several comments provided in the survey indicated concern that consumers need more information about the possible risks and that labelling was the best way to provide that information.

Public awareness campaigns about medications remain important and should be promoted to consumers where possible, including through use of technology such as apps for smart phones.

Painaustralia would welcome a review of existing public awareness campaigns and resources conducted by the Department of Health. Painaustralia can support a review process by identifying what information is required and how it is communicated and can use its consumer network to communicate the risks and efficacy of ibuprofen.

Recommendations:

Painaustralia recommends the department ensures the continued adherence to high standards of labelling and information for consumer awareness.

Painaustralia recommends a review of existing public awareness campaigns and resources about ibuprofen in consultation with consumers.

Consumer information

Best-practice pain management

Painaustralia notes the indication for OTC ibuprofen is that it be used for acute pain for not more than 4 days. Yet with Australia's pain burden escalating and one in five Australians living with chronic pain,³ it is likely to also be used to alleviate chronic (ongoing or persistent) pain which is experienced for three months or more.

Painaustralia's recent Real Relief campaign⁴ was accessed by more than 3.3 million Australians to raise awareness of why new access arrangements for codeine are necessary and alternative ways to manage pain. Despite a survey of consumers showing over half supported the decision to upschedule the medication, many consumers conveyed a lack of knowledge about alternative pain treatment options.

Painaustralia notes that larger packs of ibuprofen and slow-release ibuprofen are already only available in pharmacies. Given this, pharmacy has an important role to play in ensuring consumers understand the risks and efficacy of these medications. The Minister for Health has also recently announced \$20 million for Pain MedsCheck, a new trial program to be run in community pharmacies to support pharmacists to assist patients who are taking medication for chronic pain by evaluating a patient's medicine and the pain management program, ensuring it is supporting their clinical need and providing the best support.⁵

While this program is welcome, consumer education on both quality use of medicines and best-practice pain management options will require resources and involvement of all spheres of the health sector.⁶

By equipping consumers with more knowledge about pain and best-practice pain management treatments, they will be better able to seek out treatments that include non-pharmacological options and effective multi disciplinary, holistic approaches. Consumer awareness is also often the first step for towards adopting self-management strategies that are proven to improve activity, reduce disability and keep pain to a minimum.

Painaustralia reiterates its call for the adoption and implementation of the National Pain Strategy by the Australian Government which provides a blueprint for the treatment and management of pain and identifies the key priorities for action.⁷ A key goal and action plan to enable knowledgeable, empowered and supported consumers is central to the Strategy.

Recommendations:

That consumer awareness of best-practice pain management be supported.

Conclusion

Painaustralia welcomes the opportunity to provide input to this interim decision which will affect millions of Australian consumers, including those who live with chronic pain.

The issues raised by the review of ibuprofen scheduling such as reliance on medications for pain relief and low levels of consumer awareness, highlight the need for a national pain strategy to deliver best-practice pain management that includes quality use of medicines and an evidence-based multidisciplinary approach.

Painaustralia welcomes any opportunity to work with government to address the issues outlined in our submission or provide any additional information or feedback.

References

- 1 <https://www.tga.gov.au/book-page/16-ibuprofen>
- 2 <https://www.tga.gov.au/sites/default/files/medicines-review-nsaid.pdf>
- 3 <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4841.0Chapter12011>
- 4 <http://realrelief.org.au/>
- 5 <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2018-hunt010.htm>
- 6 <http://www.painaustralia.org.au/getting-help/right-care/self-managing-chronic-pain>
- 7 <http://www.painaustralia.org.au/improving-policy/national-pain-strategy>

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