

Painaustralia's National Medicines Policy Submission

Our submission

Painaustralia appreciates the opportunity to provide input into the Department of Health's consultation into the Revised Draft (the Draft) of the National Medicines Policy (NMP).

Painaustralia is the national peak body working to improve the quality of life of people living with pain. Members include pain and other specialists, health practitioners, health groups, consumers and researchers.

Chronic pain is complex and each person experiences it differently. Pain is a medical condition in and of itself. It can also occur in various forms at multiple sites in the body at the same time. Arthritis, back pain, migraines, fibromyalgia, complex regional pain syndrome and musculoskeletal conditions are just some of the conditions related to chronic pain, all of which generally require some form of medication treatment.

Painaustralia provided a submission in October 2021 to the NMP consultation which informed the development of the Draft, where we recommend greater consumer input into the decision making under the NMP.

With the burden of chronic disease only increasing into the future, the NMP should be a document with real levers, practical timelines and the consumer voice needs to be in very decision-making process. Consumers need policies that have **real life impact** and people living with chronic pain need action on key issues relating to **cost** and **access** to medicines that the Draft fails to address. Indeed, the consumer voice **must** be involved in every decision-making process of the NMP.

Painaustralia supports the need for one agency to be held responsible, otherwise there is a risk that the policies under the NMP will not be implemented. Painaustralia suggests that the Health Department be responsible for the NMP with input from other areas of government.

It has been 20 years since the NMP was created and there are no definitive markers for whether it has been a success. Even if the NMP review period is reduced to five years, as has been proposed, it does not serve consumers to repeat the mistakes of the past by failing to clearly outline success measures and who is responsible for their implementation.

Painaustralia generally has no concerns with the content but takes issue with the lack of planning or detail regarding how the NMP is to be implemented, practical timelines, how success is measured and who is responsible either for individual areas or the policy as a whole.

Painaustralia's submission contextualises the role the NMP can and should have to result in meaningful impact for people living with chronic pain.

Painaustralia National Medicines Policy Submission

The need for clear, measurable and actionable goals

Painaustralia's October 2021 submission called on the draft NMP to be outcomes focused; recognise the critical role of the NMP to address chronic disease; include the consumer voice at every decision-making process and, focus on implementation of the NMP including goals, measures, reporting and review frameworks.

The Draft fails to adequately address any of these points. The language surrounding the outcomes stated in the NMP are vague, generalised and lack accountability. The role, impact and demands arising from chronic disease is not contextualised nor is the term 'chronic' even mentioned in the Draft.

The implantation plan needs further detail and should form part of the Draft, rather than be developed subsequently. One issue with this approach is, for example, without clearly understanding how the States and Territories can, if they will or if they must implement the NMP, it might result in inconsistent or ineffectual application of its principles that will ultimately fail to serve consumers. Further, Painaustralia notes that targeted consultation with pharmacy groups and organisations are yet to be completed and the Draft needs to be fully informed of what may arise from complete consultation with the groups who dispense medicines.

Recommendation

Stakeholders' roles and responsibilities and the impact of chronic disease need to be defined, with a clear implementation plan to support it, if the NMP is to have a real possibility of effecting meaningful change. The consumer voice should be included at every decision-making process, otherwise known as co-design.

The NMP Vision

The Vision, p.2 of the Draft: To achieve the best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment.

This vision will be realised through the creation of an environment with effective partnerships, structures and processes with defined responsibilities to support the NMP.

Painaustralia agrees with the Draft's vision. However, there is very little to disagree with or dispute in the vision statement. Taking the word 'medicines' out of it would result in the statement being applicable to any policy issue for it lacks nuance and definition. What is meant by 'best'; Australians aren't a homogenous group and have individual health needs; who is to define what is 'highly supportive' as opposed to just 'supportive'; and, how can the NMP hope to achieve the best 'social' and 'economic' outcomes for Australians when it could be argued these are out of its remit, particularly if the responsibility of partners is yet to be defined.

Painaustralia National Medicines Policy Submission

Recommendation

The explanatory section accompanying the vision needs to outline and elaborate on these points.

The NMP and Chronic Pain

Chronic pain affects the quality of life of over 3.4 million individuals and carries a significant economic burden in lost productivity and health costs which was estimated to be \$73.2 billion in 2018.¹ Clearly identifying and consolidating the links between the NMP, chronic conditions, preventive and population health needs to form part of the Draft.

If the NMP is to go some way to ensuring affordability and access, it must recognise the impact of chronic diseases and the higher treatment and management costs associated with them, including for those living with chronic pain. In the 2011-12 Australian Health Survey (AHS), 15.4% of Australians aged 15 years or older report living with chronic pain and the prevalence of chronic pain will increase to 5.23 million Australians (16.9%) by 2050.

The NMP's role in addressing chronic disease is a critical one and failure to mention of 'chronic disease' in the current NMP is a major oversight. Chronic conditions have arguably been the most significant shift in health status in the past few decades and the NMP's single morbidity focus is inadequate and will fail to serve the medicine needs of consumers with chronic conditions, now and into the future.

As the rates of chronic disease and multimorbidity are increasing in Australia², the NMP needs to clearly define its part in highlighting the important role that medicines play in preventive care and the multidisciplinary health approach.

Recommendations

- The NMP must outline how it relates to the National Preventive Health Strategy and other Government endorsed health-related strategies and plans, including the National Strategic Action Plan for Pain Management.
- A section in the NMP should focus on how it will facilitate timely access and ensure affordability of medicines for people with chronic conditions.

¹ Painaustralia: The Cost of Pain in Australia. Deloitte Access Economics. 2018

² Australian Bureau of Statistics (ABS). Chronic Conditions. <https://www.abs.gov.au/statistics/health/health-conditions-and-risks/chronicconditions/latest-release>

Painaustralia National Medicines Policy Submission

Costs of Treatment

Medicines are the cheapest and easiest form of therapy to access in treating and managing chronic pain. For many people living with chronic pain, alternative treatment such as pain specialists and allied health services are unaffordable or inaccessible due to protracted wait times. Out-of-pocket cost for alternative treatments, and increased visits to GPs, allied health and pain specialists, were significant barriers to treatment cited by consumers in attempting to manage their chronic pain.

People with chronic pain are often unable to work, with 40 per cent of early retirement due to chronic pain, which impacts on consumers ability to pay for treatment and services.³ A report from the Grattan Institute found that in 2020-21 nearly half a million Australians decided not to see a specialist because they could not afford it. Many more did not fill a prescription because of the cost. Furthermore, people in rural areas face additional costs associated with travel and lack of access to services, which results in an over reliance on medication for their condition – a circumstance made worse by changes to how medicines such as opioids and codeine are regulated. Therefore access to less expensive medicine is vital and any changes in policy impacting access to medications need to include the consumer voice.

Restricted Access to Medicines

Best practice approach to pain management advises that drugs such as opioids should generally not be used for no longer than 3 months.⁴ However, policy sometimes fails to consider real life impacts and the need to balance safety and access, based on an individual's needs.

Due to a lack of services and extremely long wait times across the country for pain specialist treatment, medicines are often the mainstay of treatment for people living with chronic pain. Some medicines such as paracetamol and non-steroidal anti-inflammatories can play a role within a multidisciplinary, best-practice approach to managing chronic pain for many consumers. Analgesics such as pregabalin, opioids, aspirin, paracetamol and paracetamol with codeine are among the most prescribed drugs in Australia, all of which are for pain relief.

The Australian Government introduced regulatory changes to the prescription of opioids as well as access to Modified Release Paracetamol for the management of pain. These changes came into effect from 1 June 2020 and were part of a suite of measures intended to support appropriate use of opioids, multimodal medicines and other pain medications, changes to clinical guidelines and ongoing prescription and compliance monitoring.

³ Painaustralia: The Cost of Pain in Australia. Deloitte Access Economics. 2018

⁴ NSW Therapeutics Advisory Group: <https://www.nswtag.org.au/wp-content/uploads/2018/06/1.8-Deprescribing-Guide-for-Regular-Long-Term-Opioid-Analgesic-Use-in-Older-Adults.pdf> | See also: <https://www.healthdirect.gov.au/opioid-medicines> .

Painaustralia National Medicines Policy Submission

These changes coincided with the pandemic and the national rollout of Real Time Prescription Monitoring programs. All these factors combined have contributed to limiting consumer access to medications but hardly any readily accessible and affordable alternative treatment options. While there is a need to be conscious of the harm that can result from opioid use, consumers should not be inappropriately denied access to the necessary pain management options they need. Denying access is not only cruel but also dangerous. Denying citizens agency damages their relationship with government and any changes to access to medication should be implemented with appropriate regard to individuals who live with chronic pain. As fought for by Painaustralia founder Dr Michael Cousins and stated in the Declaration of Montreal access to pain management is a **fundamental human right**.

Painaustralia conducted a consumer survey on the impact of the opioid regulatory changes⁵ and received an overwhelming response with more than 1800 respondents. Since the reforms were introduced, a total of 37.7 per cent of respondents said their opioid medication had been reduced by a health professional and total of 18.5 per cent had their medication ceased (table 4). 61 per cent of respondents who had their medication ceased or reduced said they would like to be more involved in the decision regarding their medication.

Many respondents were concerned that their medications had been stopped or were reluctant to go to a GP in case their medication was ceased immediately. There were also reports of rapid opioid tapering with a lack of support or guidance from their prescribing health professionals. Rapid opioid dose reduction is a concern as it can pose risks such as more severe pain and neuropsychological effects.

Overwhelmingly, survey respondents reported they were worse off since the introduction of the opioid reforms. When asked to compare their chronic pain condition in the 12 months before the opioid reforms (June 2019 to June 2020) and the 12 months after the reforms (June 2020-2021), over half of the respondents (52.5 per cent) said the management of their chronic pain had worsened in some way. Only 5.6 per cent said it had improved. A majority 53.3 per cent attributed their worsening pain to the opioid reforms negatively impacting on their quality of life.

This is an example of where an effective and accountable NMP could have prevented or mitigated the impact of the regulatory changes. This is an example of where a responsive and consultative NMP could have served consumers better. These changes were not implemented properly and had unintended and harsh outcomes, further exacerbating the issues faced by people living with chronic pain. Painaustralia is concerned that the Draft does not do enough to ensure situations like this do not happen again.

Since 2018, when codeine was unscheduled, we have seen a trend of reforms which have further eroded available treatment options for this cohort. The compounding effects of these reforms have been disastrous for the chronic pain cohort by restricting their access and leaving them with few low cost and easily accessible treatment options.

⁵ Painaustralia. Survey Report: Impact of opioid regulatory reforms on people living with chronic pain. April, 2022.

Painaustralia National Medicines Policy Submission

Table: Reforms continue to reduce treatment options for chronic pain

2018: Codeine Upscheduling	2020: Opioid Reforms	2021: Real Time Prescription Monitoring	2022: Paracetamol
All medicines containing codeine require a prescription.	Restricted access to opioids and modified release paracetamol.	Nationwide rollout of RTPM creates barriers to accessing medication.	Currently underway, the proposed changes would make accessing paracetamol more difficult.

Recommendations

- Processes to improve consumers consultation prior to the implementation of regulatory changes to medicines and a review of its impacts, including directly from consumers, should form part of the NMP.
- Funding should be allocated for continuous and additional education and awareness for both consumers and health professionals regarding any regulatory changes which may impact their medication options.

Codeine Price Hikes and Communication

In 2018, the price of codeine increased with little to no warning or consultation leaving many consumers paying more for a critical therapy to help them manage their condition. The sequence – consider, consult then communicate – should form part of the foundational approach to regulatory changes and be included in the NMP. This would ensure that consumers are not caught by surprise by changes to access or availability of their medicines and understand why the decision was made.

Consumers should be educated about the real-life impacts of the NMP. Clear messaging regarding decisions and changes to medicines-related policy needs to be considerate of the implications for specific consumer groups.

These messages need to be developed with consumers and stakeholders who are knowledgeable about the nuances of specific conditions and cohorts, and how medicines are utilised in these groups. The consumers affected and resulting potential benefit or harm must be considered before making changes to medicines policy.

Recommendation

Regulatory change consultation mechanisms that assess consumer impacts must be included in the NMP. These mechanisms should engage multiple health consumer groups relating to the condition for which the medicine is indicated for.

Painaustralia National Medicines Policy Submission

Conclusion

Without a clear focus on chronic conditions and a defined implementation plan with consumer co-design and stakeholder buy-in the NMP risks sitting on the shelf without the ability to enact real change.

The Draft in its current form is inadequate to serve the needs of people living with chronic pain and other conditions who rely on medicines for their health. Although it is a high-level document, it does still need clearly articulate who is involved and in what capacity and responsibility they will have for the goals they are to deliver.

The adage 'what gets measured gets done' is particularly relevant in this context, given that the Draft does not currently measure anything nor define who will do it. Consumers deserve an NMP that will include them in every step of the decision-making process and result in meaningful change in how medicines policy is regulated in Australia.

Thank you for the opportunity to provide input into the consultation.

