

painaustralia

NATIONAL MEDICINES POLICY

OCTOBER 2021





Painaustralia welcomes the opportunity to provide input into the Department of Health's Review of the National Medicines Policy (NMP). Painaustralia acknowledges the need to update the NMP to ensure it reflects the significant changes in the health landscape since it was developed 20 years ago.

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.

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 \$75.47 billion in 2020.¹

Chronic pain is complex and each person experiences it differently. There is not always a cause for chronic pain and it can be a symptom of another disease or a stand-alone condition. 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 short to long term medication treatment.

Painaustralia notes that the NMP is a high level document and is generally supportive of the proposed changes that are to be included in the revised version. However, Painaustralia notes a lack of focus in the document on implementation including goals, measures, reporting and review frameworks which should be addressed in future versions.

Painaustralia's submission is provided in the context of the impact of the NMP on people living with chronic pain before addressing each question in the Discussion Paper.

MEDICINES AND CHRONIC PAIN

Medicines are the mainstay of treatment options 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.

While medicines in isolation are not considered optimal in treating chronic pain, in some circumstances an individual may have tried various non pharmacological treatments without success. In these cases, doctors might prescribe medications such as opioids or benzodiazepines, although they are not generally recommended for long term use for chronic pain due reduced efficacy, and potential for harm and dependence.

In Australia, more people die from opioid related causes than the national road toll,² but medication has played an increasing role in managing pain, and over-reliance on opioids is an unfortunate symptom of a system that is not working as it should for many people with chronic pain.

The scarcity of pain specialists nationwide and long wait times, combined with the need for greater consumer and health professional awareness about better approaches to pain management, means consumers have few options besides high risk medicines. Medicines remain the most accessible and affordable treatment option to manage chronic pain.

Due to recent opioid restrictions consumers' access to these medications have been made more difficult. The national rollout of Real Time Prescription Monitoring (RTPM), has the potential to minimise harm for consumers but access to medications must not be further compromised, particularly in the absence of readily accessible and affordable alternative treatment options.

It is within this context that Painaustralia's responses to the Review are informed.

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

2. Australia's Annual Overdose Report 2020. <https://www.pennington.org.au/wp-content/uploads/Australias-Annual-Overdose-Report-2020.pdf>. Pennington Institute.

TERMS OF REFERENCE AND RESPONSES TO THE CONSULTATION DOCUMENT QUESTIONS

The review is aimed at identifying any gaps in the NMP's objectives, partnership approach and accountabilities. Painaustralia has attempted to provide high level, universal advice, as requested by the Review Committee, but outlined the experience of those living with chronic pain when relevant.

Question:

Are these proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?

Proposed Principles:

- **Equity** – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of background or personal circumstance.
- **Consumer centred approach** – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy's objectives.
- **Partnership based** – establish and maintain active, respectful, collaborative, and transparent partnerships, to harness stakeholders' skills, experience, and knowledge.
- **Accountability and transparency** – all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of the policy's objectives, within a transparent framework.
- **Stewardship** – all stakeholders have a shared responsibility to ensure that the policy's objectives are met in an equitable, efficient, and sustainable manner, as stewards of the health system.

Painaustralia Response

Painaustralia supports the general principles proposed in this Review. They are positive aspirational statements that will ultimately benefit consumers only if they are supported by a strong and effective implementation framework that includes specific outcomes measures that are reported, reviewed and regularly evaluated.

Painaustralia suggests adding a principle of being 'outcomes focussed'. A criticism of the NMP raised by many stakeholders and particularly consumers is that it is unclear how the success or impact of the policy is measured, if at all.

As a critical component of Australia's health policy, consumers need and deserve real improvements in national medicines policy. If this document is to have impact for consumers, it must include specific and measurable outcome measures.

The NMPs Four Objectives

1. Timely access to the medicines that Australians need, at a cost that individuals and the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines; and
4. Maintaining a responsible and viable medicines industry

Question:

Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?

Painaustralia Response

Painaustralia believes that the NMP's four objectives are still relevant. However, while the NMP's role in addressing chronic disease is a critical one, there is no mention of 'chronic disease' in the current NMP. Chronic conditions have arguably been the most significant shift in health status in the past 20 years and are projected to increase in the coming decade.

The NMP ostensibly reflects a 'single morbidity managed by one medicine' framework. As the rates of chronic disease and multimorbidity are increasing in Australia³, the NMP provides an opportunity to highlight the important role that medicines play in preventive care and the multidisciplinary health approach as part of an evidence-based holistic treatment plan. The NMP should 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.

Clearly identifying and consolidating the links between the NMP, chronic conditions preventive and population health should be considered as a stand-alone objective.

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

Question:

Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?

Painaustralia Response

Devices

Painaustralia supports the definition of medicines being expanded to include medical devices and vaccines. Painaustralia's position is that the physical form of a treatment is less relevant than its intended therapeutic effect. Devices now act as medicine and medicines are no longer just a pill.

The availability of drug pump therapy, an advanced treatment option for chronic pain patients who haven't achieved enough pain relief with other treatments, is an example of how the distinction between device and medicine is considerably blurred. Invasive medical devices intended to administer medicines or biologicals by inhalation are also widely used for the treatment of respiratory disorders and more recently, the use of aerosols has expanded to non-respiratory conditions (for example, diabetes).

Any product that claims to provide a therapeutic benefit should be governed by a consistent regulatory framework that benefits and protects consumers. Medicines face much stricter regulatory standards, including in advertising products directly to consumers, than devices. Some medical devices are promoted to consumers as having certain therapeutic benefits, without having the robust evidence base or penalties in place that are required for medicines.

Medical device companies should be regulated and held to the same standard as pharmaceutical companies to ensure that consumers are not offered ineffective and potentially harmful treatments.

The NMP should provide a clear definition of medicines which captures devices that act like medicines. Doing this would also ensure that the NMP remains relevant in the future when we will see advancements in medical technologies that will conflate these distinctions even further.

Vaccines and prevention

Painaustralia sees merit in including vaccines in the expanded definition of medicines as an important tool in prevention of disease.

It is also timely that the revised NMP include a focus on prevention and early intervention as a cost effective way to address chronic disease.

Question:

Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?

Painaustralia Response

The title of the NMP is less important than ensuring a clear and comprehensive definition of the term 'medicines'. The definition needs to include devices that act like medicines, which focuses on the therapeutic effect of a good rather than its form.

Question:

How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?

Painaustralia Response

It is arguable that the NMP is no longer fit for purpose.

Advancements in precision medicine will bring forth unforeseen challenges and opportunities for consumers. The speed of progress will continue to surpass the ability of governments and policy makers to respond, and this gap will only increase into the future unless rigorous mechanisms are built into regulatory and policy-making processes to accommodate this rapid change.

What must be recognised in the pursuit of advancing medical technologies is the primacy of consumers' needs. To ensure that consumers are prepared and equipped for this rapidly evolving landscape, consumer health literacy must be improved, and greater awareness of treatment options and best practice approaches must be promoted.



Advances in technology will give more power to the consumer to manage their health and access to information than ever before. This includes:

- greater access to health data
- automation of health systems including in prescribing and dispensing
- the proliferation of mobile devices, and
- increase in the development and numbers of healthcare related applications.

The increase in connectivity and efficiency gains provided by digital health may also continue to result in a sharper divide between consumers who have resources and education to navigate more complex health policy and those who do not.

Consumers will speak to an App rather than a pharmacist; search information online rather than seeking guidance from their GP; and the availability of online information, especially if inaccurate or misleading, will lead to poor quality use of medicines.

The NMP must recognise that the medicines policy landscape is not static. It must serve consumers as developments in health technologies occur, not after they have hit the market or their impacts having already occurred.

Question:

How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?

Painaustralia Response

The NMP must be a living document and needs to have built in robust measurement, reporting and review mechanisms. Regular reviews could be scheduled wherein a targeted, issue-specific taskforce could be established to update or amend sections of the NMP as needed

An example of this how this more robust framework would apply is when the Government announced in June 2020 that it was changing how opioids are prescribed to reduce harm in the community.



While the potential harm and risk of dependence is well known, and the Government's harm minimisation effort should be commended, the changes failed to adequately consider the 3.4 million Australians living with chronic pain, as for many, opioids are the only effective treatment for their long-term condition. The NMP objectives, if applied and considered in this context, would have necessitated an assessment of potential impact to consumers and implications for all stakeholders to reduce the risk of unintended consequences.

The NMP needs a rigorous feedback mechanism for consumers and stakeholders to communicate what is happening on the ground for consumers.

Question:

How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?

Painaustralia Response

Painaustralia welcomes the participation of a consumer representative and heads of consumer organisations in developing the NMP Terms of Reference and on the Review Committee. The inclusion of consumers on several initiatives related to the NMP, such as consumer representation on TGA and PBS advisory committees, is also a positive step.

However, a broad-brush approach to consumer representation provides limited benefit when what is required is nuanced knowledge of specific conditions such as chronic pain. Along with this general consumer approach, Painaustralia would also welcome the participation of consumers who are living with or affected by the condition and use its related medication as part of future Government consultation processes.

When particular decisions impacting consumers such as those outlined recent in Painaustralia's submission to the recent *Parliamentary Inquiry into Approval Processes for New Drugs and Novel Technologies in Australia*⁴ are considered, specific and diverse consumer input should be sought to inform decisions.

Question:

What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?

Painaustralia Response

A committee that oversees the NMP, comprising consumers, health organisations, health professionals and industry representation should be established to document how all the NMP's related documents and initiatives work together. The former Australian Pharmaceutical Advisory Council provided this oversight at the establishment of the NMP. The removal of this body has reduced the accountability for delivery of robust medicines policy.

4. Painaustralia Submission to the Inquiry: <https://www.painaustralia.org.au/static/uploads/files/inquiry-into-approval-processes-for-new-drugs-and-novel-medical-technologies-in-aus-wfyrrpayyemgk.pdf>

This committee's focus must be to establish rigorous measurement, reporting and evaluation frameworks and to obtain regular feedback from multiple stakeholders who are engaging with consumers on a regular basis. The NMP's governance arrangements and work program should be informed by consumers at all levels.

Question:

How can communication about the NMP be enhanced or improved?

Painaustralia Response

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 should be considered before making changes to medicines policy. These considerations should then inform a multichannel, multimedia communication strategy which leverages available technologies and platforms. The sequence – consider, consult, decide, then communicate – is crucial to ensure that consumers are not caught by surprise by changes to access or availability of their medicines, and understand the rationale for the decision made.

An example was when codeine was rescheduled from an over-the-counter drug to one requiring a prescription. Painaustralia was involved in a campaign to educate consumers about the changes and utilised various forms of social media and media channels. Our issue specific knowledge resulted in an increase in understanding and support of the changes from 23% in support of the government's policy pre-campaign to 50% post.

Question:

What would be effective mechanisms to support communication about the policy?

Painaustralia Response

Communication about the NMP would be enhanced by consideration given to what mechanisms are required to achieve change are, the likely impact that communication can achieve, and what channels will best deliver nuanced messaging for different audiences, including hard to reach groups. Engaging multiple health consumer groups to deliver messaging through their diverse networks as well as reaching the broader community are important considerations.

Question:

- How should the NMP's 'partnership-based' approach be defined?
- What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?
- How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?
- How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?

Painaustralia Response

While partnerships are an important feature of the NMP model, it is important that a fit for purpose approach to particular aspects of the NMP be applied specific to outcomes.

Without clear, defined metrics, key performance indicators and outcomes measures, and how they inform an implementation strategy, it is difficult to determine who the partners should be in what capacity.

The NMP requires regulatory levers to encourage or enforce accountability. Without consequences or incentives, the NMP risks being an aspirational government policy document, rather than a framework for achieving meaningful change for consumers.



In summary, Painaustralia supports the review of the NMP and urges an indication of a clear implementation plan including timeframes and priorities.

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

painaustralia

Mailing address: PO Box 9406 DEAKIN ACT 2600

Phone: 02 6232 5588

Email: admin@painaustralia.org.au

Website: www.painaustralia.org.au