Response to the Australian Government Department of Health

Review of the National Medicines Policy

Consultation
October 2021

Introduction

Palliative Care Australia (PCA) is the national peak body for palliative care. PCA represents those who work towards high quality palliative care for all Australians who need it. Working closely with consumers, our Member Organisations and the palliative care workforce, we aim to improve access to, and promote palliative care.

PCA Response to the Review of the National Medicines Policy

PCA welcomes the opportunity to contribute to the review of the National Medicines Policy (NMP). There are four overarching **key issues** that PCA would like to highlight in relation to the NMP and its impact on people living with life limiting illnesses and accessing palliative care:

1. **Appropriate prescription of opioids for palliative care patients**
   There is increasing focus at a government and regulatory level in Australia regarding opioid prescribing for chronic non-cancer pain. In an effort to reduce inappropriate prescribing that can lead to harm from misuse and abuse of opioids, palliative care patients are being placed at risk of unintended harm through reduced or ceased opioid prescribing. In particular, General Practitioners (GPs) need to be supported to provide appropriate treatment to patients with life limiting illnesses, including appropriate pain management, without fear of sanctions.

2. **Real Time Prescription Monitoring**
   Advancing real time prescription monitoring will build better protection against misuse of opioids, and further support the appropriate use of opioids for pain management in patients with life limiting illnesses. PCA believes that national real time monitoring for all opioid prescriptions with software that is enabled to identify palliative care prescriptions at point of care across the acute, sub-acute, aged care and primary care sectors will improve patient safety, supporting the quality use of medicines framework and improve data collection for research and regulation purposes. National real time prescription monitoring whilst designed mainly to reduce misuse could also be used as a tool to support medication reconciliation of the dose/type of opioid especially as people move between clinical settings. This may also stop hesitancy about new scripts if a clinician has real time data about when supply has run out or is expected to run out.

   PCA sees pharmacists, community and hospital based, as critical to palliative care multi-disciplinary teams. Their role in real time prescription monitoring will be essential to ensuring the safety of patients with life limiting illnesses.

3. **Limited suppliers of critical palliative medicines**
   There have been instances where there has only been one licensed supplier in Australia for certain palliative care medications. This has caused significant problems when the only supplier withdraws from the market. Patients suffer as it can be difficult to source alternatives or they can be prohibitively expensive. PCA would like to stress the importance of having more than one supplier of key palliative care medications operating in the market at all times.

4. **Affordable Access to Medicines**
   PCA believes that quality palliative care should be available to Australians when and where they need it. A fundamental component of this is being able to obtain the palliative medications they need to manage pain and symptoms. PCA strongly supports the current objective of the National Medicines Policy:

   - *Timely access to the medicines that Australians need, at a cost individuals and the community can afford.*

   This objective recognises that access to medications relies on affordability for patients and consumers.

As the peak body for palliative care in Australia, PCA has a key interest in ensuring the success of the National Medicines Policy. Palliative care patients rely on medicines for a significant component of their care to manage and control their pain and symptoms associated with their life-limiting illness/es. PCA has had a very good working relationship with the Australian government agencies responsible for the regulation and funding of medicines including the Therapeutic Goods Administration (TGA), the Pharmaceutical Benefits Advisory Committee (PBAC) and the Technology Assessment and Access Division of the Department of Health.

PCA has actively led in medicines policy for the palliative care sector by working with other health bodies to achieve consistency in recommendations for improvement, particularly in aiming to ensure sustainable access to prescription opioids. PCA released the Position Statement Sustainable Access to Prescription Opioids for use in Palliative Care in 2020. The key messages from the Statement are:

- All Australians receiving palliative care must be able to access necessary opioids to manage and prevent suffering from uncontrolled pain and other symptoms.
- In an effort to reduce inappropriate prescribing that can lead to harm from misuse and abuse of opioids, palliative care patients are being placed at risk of unintended harm through reduced or ceased opioid prescribing.
- There is a need to increase the understanding of appropriate use of opioids within the Australian palliative care context and provide leadership and guidance in resultant regulatory processes for the community and prescribers.

The Statement outlines eight recommendations in relation to the management of opioids for people with life limiting illnesses receiving palliative care.

1. All prescribers are enabled to access appropriate opioids (oral and parenteral) consistently for pain and breathlessness management for people living with life-limiting illnesses, without the burden of unnecessary regulatory barriers.

2. Compulsory palliative care and opioid management education for all medical, nursing, allied health and pharmacists to be built into undergraduate curriculum to ensure a consistent baseline competency in pain and symptom management.

3. Ensure an adequate supply and stock (imprest) of minimum levels of opioids commonly used in palliative care including parenteral formulations in acute facilities, community pharmacies and out of home settings such as residential aged care facilities and prisons, with processes in place to manage planned or emergency shortages.

4. Nationally consistent and streamlined prescribing approval policies for opioids that promotes pain and addiction specialists working closely with palliative care. This will ensure patients with opioid dependency are recognised as a group of patients with increased complexity in pain and symptom management in the setting of a life-limiting illness.

5. The introduction of national real time monitoring for all opioid prescriptions with software that is enabled to identify palliative care prescriptions at point of care across acute, sub-acute, aged care and primary care sectors. This will improve patient safety championing the quality use of medicines framework and improved data collection to further inform research and regulation.

6. Palliative care teams to work with acute services to develop opioid stewardship policies informing clinical plans to ensure appropriate prescribing, de-prescribing, and dispensing of opioids with rapid communication to the primary care team and community pharmacy to reduce risk of forced tapering of appropriate opioid management.

7. The Australian Government to re-form the Palliative Care Medications Working Group to review the Palliative Care Schedule of the Pharmaceutical Benefit Scheme (PBS). This Schedule must meet current, evidence-based practice guidelines and an improved awareness to prescribers. [Note: PCA welcomed the Government's action to undertake such a review over 2020-21].

8. A review of the Medicare Benefits Schedule (MBS) specific to palliative care by way of item numbers and explanatory notes to facilitate consultation in primary and specialist practice. This will recognise the complex, multidisciplinary nature of symptom management plans and goals of care/ advance care planning discussions, and the different requirements of providing palliative care across all settings including home visits, after-hours support and within aged care services.

These recommendations were endorsed by:

- Australian and New Zealand Specialists in Palliative Medicine
- Australian College of Nursing
- Australian College of Nurse Practitioners
- Australian College of Rural and Remote Medicine
- Australian Healthcare and Hospitals Association
- The Australian Pain Society, Pain Australia
- Palliative Care Nurses Australia
- Paediatric Palliative Care Australia and New Zealand
- The Pharmacy Guild of Australia
- Royal Australian College of Physicians
- Society of Hospital Pharmacists of Australia.

In general terms, PCA would welcome an additional statement in the National Medicines Policy regarding the prescription of and access to pain medications for people with life limiting illnesses receiving palliative care, to articulate the need for multiple suppliers, clear prescribing regulations and ongoing support for clinicians.

PCA also provides the following comments on the Terms of Reference outlined in the discussion paper:

Terms of Reference 1: **Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.**

The principles and objectives outlined in the Discussion Paper are sound and provide a good basis for the future. In particular a focus on equity will be very important and will need to be constantly reviewed to ensure all Australians can access the medications they need.

Advances in technology, medical diagnosis and treatment have the potential to benefit the whole population and direct resources to where they are most beneficial. However, where a consumer is expected to subsidise or make a co-payment for using these technologies, inequities and discrimination in access can result. To ensure all Australians benefit from these emerging technologies and advances in medications, equity of access must be a guiding principle.

The proposed Principles to underpin the objectives of the NMP may also be strengthened with the following additions:

- The inclusion of 'carer/s' in the second principle outlining the consumer centred approach. Carer/s play a key role in the provision of palliative care, and this extends to the management of medications for the person with a life limiting illness.
- The Stewardship Principle is expanded to include systems to support prescribing clinicians. Prescribing clinicians need clear guidelines, access to ongoing education, and transparent information relating to the regulations in prescribing opioid medications to patients with life limiting illnesses receiving palliative care. This cohort of patients require adequate access to pain medications without their prescribing clinician limiting access for fear of non-compliance with existing regulations to manage over-prescription in the non-palliative care environment.

PCA believes the objectives outlined in the National Medicines Policy (2020) are still relevant:

1. timely access to the medicines that Australians need, at a cost 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.

In relation to objectives two and three, a key barrier to improving appropriate prescribing of opioid analgesics is a lack of understanding about patients who are at risk of opioid misuse as compared to palliative care patients who need appropriate and often higher doses of opioids for longer periods to manage their pain and symptoms. Treatment of chronic pain with long term opioids and use of opioids at the end of life are two different issues.[1]

The appropriate prescribing of opioids should not be limited to a framework solely for <u>restriction</u> of use, but rather support for appropriate dosing (which will often mean increased dosing) for palliative care patients. Otherwise, the greater risk may be that staff's fears will lead to underuse of opioids and patients dying in pain.[2]

[1] Mitchell, G., Willmott, L., White, B., Piper, D., Currow, D., and Yates, P. (2019), A Perfect Storm: Fear of Litigation for End of Life care. *Medical Journal of Australia* 210 (10) 441.

[2] Gerber, K., Willmott, L., White, B., Yates, P. Mitchell, G., Currow, D. and Piper, D. (2021), Barriers to Adequate Symptom Relief at the End of Life: A Qualitative Study Captures Nurses' Perspectives, Collegian, 19:25.

As has been noted by Willmott *et al, e*very day, thousands of health professionals provide medical treatment to Australians as they approach the end of their lives. An important component of that medical treatment is provision of medication to alleviate pain and other symptoms. So that patients can experience the best possible medical care at the end of life, it is critical that medical treatment can be provided by health professionals who are not constrained by ill-informed concerns about potential or even likely legal or disciplinary consequences of providing pain and symptom relief that may incidentally hasten a patients' death. The available anecdotal evidence in Australia suggests that under-medication of patients may be happening because of concern about potential regulatory repercussions of providing that treatment.[3]

Therefore, more education is needed to alleviate such fears and help staff feel confident in their practice and supported by the law. This may point to the need for health practitioners to have better understanding about the true nature of the regulatory risk so health professionals can practise treating palliative care patients with confidence.

Health professionals should use both treatments and doses that are clinically indicated to alleviate the person's suffering. Opioids should not be avoided, and the minimum dose that achieves pain relief or reduction of chronic breathlessness should be prescribed. In some cases, the dose may appear very large, but as long as titration to that dose occur steadily, the risk of adverse events such as respiratory depression being induced by the treatment is negligible. Clinical practice that seeks to alleviate suffering will be respected by the law and not punished.[4]

PCA notes that the fourth objective "maintaining a responsible and viable medicines industry" is a challenge in the field of critical palliative medicines which should be addressed. Recently, in Australia, there have been situations where there is only one supplier of key palliative care medications and if/when that supplier withdraws the market (and there have been recent cases of this), prescribers and patients are put in a very difficult situation, often with unnecessary pain and suffering the result for patients. This objective would be strengthened by the inclusion of a comment to the effect that multiple suppliers in a given market provide improved access and decreases the monopolising of a market segment.

Terms of Reference 2: Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

This is an emerging application in palliative care so at this time PCA does not have further to comment about this term of reference.

Terms of Reference 3. **Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.**

As noted in the Discussion Paper, the NMP does not currently include reference to access to clinical trials. As a significant treatment option for patients with cancer diagnoses, PCA would welcome a statement in the NMP regarding access to clinical trials with regard to equitable access, particularly for those patients not residing in capital cities. In addition, new symptom control medicines are being developed for patients with life limiting illnesses, and clinical trials will be undertaken. It is important that there is equity of access to these trials as well.

[3] Willmott, L., White, B., Piper, D., Yates, P., Mitchell, G. and Currow, D. (2018) Providing Palliative Care at the End of Life: Should Health Professionals Fear Regulation? 26 *Journal of Law Medicine*, 214.
[4] Mitchell *et al* (2019).

Likewise, the current NMP does not include reference to digital health – both records and consultations. PCA sees the use of digital options for the management of medications for palliative care patients and their carers as a central component of timely and equitable access and patient centred care. National real time monitoring of opioid prescriptions will improve patient safety and support appropriate prescribing of pain medications for patients receiving palliative care. National real time prescription monitoring whilst designed mainly to reduce misuse could also be used as a tool to support medication reconciliation of the dose/type of opioid especially as people move between clinical settings.

There is scope for further research on the use and benefits of off-label prescribing for symptom management. Palliative care is a health domain where clinicians have noted that drug repurposing can have significant benefits for patients.

Terms of Reference 4: **Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.**

PCA supports the outcome from the Stakeholder Forum referenced in the Discussion Paper held in (January 2020) which emphasised the need for a patient-centric focus and reference to health literacy within the NMP. Palliative care encompasses the needs of the carer as well as the patient, and as such, PCA would encourage any commentary on patient-centred care and health literacy to include carers.

Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

PCA recognises that there has been considerable work to improve governance, communications, implementation and evaluation of aspects of the National Medicines Policy. PCA has benefited from more targeted communication to support our sector over recent years which has been noted and appreciated.

PCA commissioned KPMG to undertake an investigation into the transparency gaps in the reporting of palliative care activity and expenditure in Australia. KPMG has explored the existing evidence on palliative care funding and provision and consulted with key stakeholders in palliative care to better understand the key issues and complexities in reporting about palliative care. KPMG recently completed this study and the full report can be found here: Information gaps in Australia's palliative care - Palliative Care. KPMG had autonomy to identify the potential opportunities to support quality, person-centred palliative care for more Australians through improved consolidated reporting and remedy of the issues identified in the report. KPMG identified five key opportunities – one of which is to:

Provide palliative care patients with access to the medicines they need. KPMG noted that:

> *While the recent recommendations to include additional opioid medications in the Palliative Care Schedule are welcomed, there is still a significant opportunity to ensure reviews do not follow 'set-and-forget' policies of the past, and are instead conducted routinely (e.g. every three years).*[5] *This will help mitigate barriers to patients' access to core medicines through*

[5] Department of Health (2021) Pharmaceutical Benefits Scheme (PBS) | New listings for opioid medications on the Palliative Care Schedule for the management of severe disabling pain from 1 June 2021 [online] www.pbs.gov.au . Available at: https://www.pbs.gov.au/info/news/2021/05/ new-listings-for-opioid-medications-on-the-palliative-care

reduced costs and fewer claim rejections, and simultaneously improve the administratively reported data. At present, PBS data on palliative care medicines does not cover the full range of medicines accessed for palliative care.[6] *This review, and subsequent reviews, will therefore ensure that the data more accurately represents the provision of palliative care medicines and that more Australians have adequate access to them* (page 23).

PCA supports the findings outlined by KPMG and recommends scheduled reviews of the Palliative Care Schedule of the PBS and improved collection and reporting to capture the broader range of medicines prescribed for and used by palliative care patients.

Terms of Reference 6: **Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.**

PCA believes that palliative care is core business in aged care, which has been supported by the findings of the Royal Commission into Aged Care Quality and Safety. PCA would welcome the NMP identifying aged care providers as partners, and ensure that medicines delivered to residents in aged care facilities is done so safely, and appropriately.

In response to the Australian Commission on Safety and Quality in Health Care review of the "Quality Use of Medicines in Aged Care", PCA noted that:

- 36% of all Australians who die, do so in residential aged care
- Those living in residential aged care with palliative care needs often have multiple comorbidities, and the clinical course includes intercurrent clinical problems and change in clinical status as the person deteriorates.
- Important symptoms which are common in residential aged care include pain, breathlessness and delirium, due to the nature of the medical conditions and also the frequency of dementia
- PCA supports approaches which optimise opioid management for those for whom the evidence supports benefit, that ensures all prescribers are enabled to prescribe, in a timely manner, appropriate opioids for pain and breathlessness management for residents with palliative care needs, without the burden of unnecessary regulatory barriers, with the appropriate education and training to feel confident in their appropriate use and specialist support where necessary.
- Processes for medicines review by pharmacy and medication experts (for example RMMR (resident medication management review), also need to integrate information from a contemporaneous resident clinical assessment and involve the interdisciplinary team so that advice can be tailored to the resident's individual clinical needs.

Given the significant role of residential aged care in the management of people with life-limiting illnesses, it is important to identify residential aged care as a key stakeholder and partner in the NMP and its review.

[6] Australian Institute of Health and Welfare (AIHW). (2020) Palliative care services in Australia, Palliative care-related medications - Australian Institute of Health and Welfare (aihw.gov.au)
https://www.aihw.gov.au/reports/palliative-care-services/palliative-care-services-in-australia/contents/palliative-care-related-medications