

painaustralia

**SUBMISSION TO CONSULTATION PAPER:
Prescription strong (Schedule 8) opioid use and misuse in Australia –
options for regulatory response
DEPARTMENT OF HEALTH, THERAPEUTIC GOODS ADMINISTRATION
MARCH 2018**

Executive Summary

Painaustralia welcomes this consultation, and the opportunity to provide input on the policy response to increases in the prescribing of opioid medications and related harms including overdoses, hospitalisations and deaths.

These issues highlight the urgent need for a national and holistic strategy to better prevent, treat and manage pain as a national health emergency. This issue extends beyond the remit of the Therapeutic Goods Administration (TGA) and requires a cross-portfolio and multi-level government response.

Better understanding of both quality use of medicines and best practice pain management, treatment and support is vital for both prescribers and consumers. Resources and programs are needed to address stigma; provide consumers with knowledge to seek out the most appropriate pain management options; and give prescribers the tools they need to deliver best-practice pain medicine. We are encouraged by the strong emphasis on education and alignment of regulatory approaches with clinical guidelines in the consultation paper.

Painaustralia supports the review of regulatory options as outlined by the TGA on the basis that there is proper consultation and widespread consideration of the issues raised by the many stakeholders affected by these changes.

Painaustralia has specific concerns with some of the options outlined in the submission that could have unintended consequences for consumers and those working in pain medicine.

While noting the lack of definitive evidence supporting the long-term effectiveness of opioid analgesics in people experiencing chronic non-cancer pain (CNCP) and the substantial evidence of potential harm, changes to the prescribing of opioids will have ramifications for the millions of Australians who are using these medications and this impact must be given priority consideration. Striking the right balance between safety and ensuring patients can access the treatment they need to achieve quality of life is challenging, but necessary.

A range of regulatory options need further consideration, but have not yet been realised. These have been raised in previous government-sponsored forums (for example, the Opioid Roundtable 2015 and the National Pharmaceutical Drug Misuse Framework 2012-2015) including national real-time prescription monitoring. The full implementation of this system should be prioritised over other regulatory reform options, to bring about coordinated and systemic change that would prevent opioid-related harms.

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.

Painaustralia also provides essential sources of information for consumers, medical practitioners and researchers.

Summary of Recommendations

National Pain Strategy

- That the Department of Health recognises the issues of opioid reliance and misuse will not be solved without urgent implementation of a national strategy to better prevent, treat and manage pain.
- That the Department of Health note the National Pain Strategy 2010 provides a blueprint for pain management and priorities for action, and should be implemented through COAG to ensure it becomes a national health priority.
- That the Department of Health develop a regional pain and opioid management strategy that uses a range of policy levers to bridge the pain services gap in regional areas, including options outlined by Painaustralia in its 2018-19 Pre-Budget Submission.

Education and information for Prescribers

- Painaustralia strongly supports option 8, and the prioritisation of increasing health care professional awareness of alternatives to opioids and best-practice prescribing.
- That the Department of Health consider making pain management and prescribing education for Continuing Professional Development (CPD) programs mandatory for accreditation through the Medical Board, including identifying at-risk prescribers.
- That clinician education should not be solely the responsibility of industry sponsors and alternative education opportunities are made available.
- That the Department of Health work with key partners including clinical colleges to provide current, clear, visible and accessible clinical guidelines that meet a broad range of needs.
- That the Department of Health note the best-practice model of care for chronic pain management and understand the barriers to achieving its implementation across all primary care settings.

Education and information for Consumers

- Painaustralia supports option 5 to review label warnings and revision to the Consumer Medicines Information to better support and inform consumers. This should be the subject of further consultation with consumers and industry.
- That the Department of Health note the use of regulatory approaches that target consumers must be combined with greater access to appropriate support systems and services.

Regulatory Options

- Painaustralia supports a review of regulatory options for opioid prescribing as part of a holistic and whole-of-government response to opioid reliance and misuse and the need to address pain as a national health challenge.
- Support for this review is contingent on further and formal consultation processes with a wide range of stakeholders, with a focus on unintended consequences, and Painaustralia can take an active role in facilitating these discussions through its network.
- That the Department of Health note any changes to the prescribing of opioids will directly affect many people living with pain who currently use these medications and health practitioners over the short, medium and long terms.
- That the Department of Health consider reform options that have been previously raised and prioritise the implementation of an effective national prescription monitoring system.

National Pain Strategy

The increase in the prescribing of opioid pain medications and opioid-related harms including overdoses, hospitalisations and deaths highlights the urgent need for a national and holistic strategy to better prevent, treat and manage pain as a national health emergency.

Commissioned in July 2017 to find solutions to the United States opioid 'crisis', the US National Academy of Science, Engineering and Medicine aptly stated the issues of opioid misuse 'lie at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the increasing toll of the harms that can arise from the use of opioid medications'.¹

Along with recommendations on regulating opioids, the Academy made a series of key recommendations to address pain as a public health burden including:

- investment in research to better understand pain and opioid use disorder;
- pain education materials for health care providers;
- greater access to more cost effective, evidence-based comprehensive pain management that encompasses pharmacological and non-pharmacological treatment.

Australia's pain burden is a burgeoning social and economic issue, increasing in prevalence as the population ages and chronic conditions rise. At least one in five Australians experience chronic pain² and it is the reason for up to 40% of adult general practice consultations.³ Pain impacts individuals, families, workplaces and the economy, and increasing awareness of pain is critical.

Governments, policy-makers, health practitioners and care givers must also recognise that chronic pain and opioid use disorder are complex conditions, and each can cause significant disability, social exclusion and a diminished financial situation. The TGA notes that concessional patients are prescribed a disproportionate amount of Schedule 8 opioids, especially for extended release products.⁴ This not only relates to the cost of prescriptions, but the poor access to multidisciplinary pain services that enable patients to find better ways to manage pain, increase activity and improve health and wellbeing.⁵ At least 80% of people living with chronic pain are missing out on treatment that could improve their health and quality of life.⁶

The issues of opioid misuse and overprescribing will not be addressed by pharmacological alternatives, regulatory reforms or dispensing practices alone. While each of these are important to minimise harms, systemic change across the health system and its response to pain is essential.

This has been the policy priority for those working at the coalface of pain management for some time. In 2015, the TGA convened the Opioids Roundtable to improve patient safety and manage risk of PBS listed opioids, bringing together over 70 specialists, health practitioners, pharmaceutical companies, researchers and policy makers.

The Roundtable concluded that while regulation and best clinical and quality use of medicines will drive good regulation, a much broader range of service-wide health changes were also needed, including:

- Recognising psychosocial factors influence a patient's experience of pain, their chance of developing chronic pain and their risk of opioid misuse and should be assessed at every presentation to identify a patient's vulnerability.
- Patients should be managed under a comprehensive treatment plan that considers psychosocial factors and includes multimodal strategies for pain management.
- Better system pathways and linkages between health professionals to facilitate this shared care approach.⁷

Australia is uniquely placed to advance a national response to pain as a significant health challenge, as it was the first country in the world to advance a national framework for pain through the 2010 National Pain Strategy.⁸ Developed by more than 150 stakeholders, the Strategy provides a blueprint for the treatment and management of acute, chronic and cancer pain and is an important resource for specialists, health care administrators and policy makers, identifying the key priorities for action.

While some states and territories have made commitments in line with the National Pain Strategy, adoption and implementation of the Strategy by the Australian Government and the Council of all Australian Governments (COAG) would ensure people in pain become a national health priority and the realisation of gains through prevention, community awareness, early intervention and better access to pain management services.

The principles of the Australian Healthcare and Hospitals Association's blueprint for a post-2020 national health agreement, *Healthy People, Healthy Systems*⁹ are worth considering in the context of developing a national strategy to address pain and opioid misuse. The blueprint identifies the need for a nationally unified and regionally controlled health system that puts patients at the centre of health service delivery, values holistic health and wellbeing and integrated care.

Recommendations:

- That the Department of Health recognises the issues of opioid reliance and misuse will not be solved without urgent implementation of a national strategy to better prevent, treat and manage pain.
- That the Department of Health note the National Pain Strategy 2010 provides a blueprint for pain management and priorities for action, and should be implemented through COAG to ensure it becomes a national health priority.

A Regional Approach to opioid reliance and pain management

Consumption of prescription opioid use in regional areas was much greater than in capital cities as found in a 2017 analysis of 54 wastewater sites by the Australian Criminal Intelligence Commission.¹⁰ Consumption of oxycodone and fentanyl in regional sites was well above capital city levels, with the average use of oxycodone in regional areas almost double that in capital cities.

While the prevalence of back pain and long term health conditions resulting from injury are greater in regional areas,¹¹ there are few pain services. The potential of telehealth and pain education in primary health settings to fill service gaps has not yet been realised.

A regional pain and opioid management strategy is required that uses a range of policy levers to bridge the pain services gap in regional areas, including considering access to Medicare-funded pain management services and opioid dependency programs. This is a key recommendation of the Australian Commission on Safety and Quality in Health Care which also revealed opioid medications were being subscribed in some regional areas at 10 times the rate of other sections of the population.¹²

Key priorities that would address the regional pain services gap are highlighted in Painaustralia's 2018-19 Pre-Budget Submission¹³ and include:

- Greater access to online management support programs;
- Establishing mini-pain programs in Primary Health Networks; and
- Expand telehealth options to support more pain services in regional area.

Recommendations:

- That the Department of Health develop a regional pain and opioid management strategy that uses a range of policy levers to bridge the pain services gap in regional areas, including options outlined by Painaustralia in its 2018-19 Pre-Budget Submission.

Education and information for Prescribers

Painaustralia strongly support option 8. We recognise the importance of appropriate clinician education on pain assessment and management, including prescribing, is critical to the realisation of other regulatory approaches outlined by the TGA. This includes a review of indications for strong opioids, noting the inconsistency between products and members of the class and the need to align them to the current clinical guidelines (option 2); the strengthening of risk management plans for opioid products (option 4); and additional prescribing controls for strong opioids using appendices in the Poisons Standard (option 7).

These principles should be integrated into Continuing Professional Development (CPD) programs and be considered mandatory, like other essential skills for medical practitioners. Referral for pain and opioid prescribing education should form part of the professional performance framework for medical practitioners deemed to be at risk, as determined by the Medical Board of Australia (MBA).¹⁴ This would create an incentive to support practitioners to receive this training, particularly where they are geographically isolated, have overseas training or have been practising for some time and require updated training on pain management and prescribing that reflects new evidence.

Concerns with prescribers who are identified by the relevant bodies, or through the real-time monitoring system, could also be referred for education through this process.

While the consultation paper notes the NPS MedicineWise resources, the Better Pain Management learning modules provided by the Faculty of Pain Medicine (FPM) are also important.¹⁵ We also note the Royal Australian College of General Practice (RACGP) have updated their prescribing guidelines for drugs of dependence in primary care and other coursework is offered by the NSW Agency for Clinical Innovation (ACI) and Pain Management Research Institute (PMRI) University of Sydney.

While noting the best efforts of some industry sponsors to provide education activities, this should not be left to industry alone and should have the input of clinical groups and medical colleges.

We note the recent review of CPD and that the Australian Medical Board Professional Performance Framework has recently been updated. Consideration to the evolving nature of Continuing Professional Development is critical¹⁶ and should include the involvement of GPs. It could include case-based education that could be conducted in small groups and structured peer support networks to discuss complex cases. There may be a role for Primary Health Networks to hold education events¹⁷ and train-the-trainer pain educator models will also be critical to expand access in regional areas.

We note that achieving this outcome will be beyond the powers of the TGA, but a whole-of-portfolio approach and the involvement of other agencies is required to address the issues of opioid misuse. The Faculty of Pain Medicine must be a key partner in achieving this goal, together with federal and state health departments, relevant clinical colleges and the National Prescribing Service.

Greater awareness of pain management is essential to moving away from a reliance on medications. The third goal of the National Pain Strategy is that 'skilled professionals will support people with pain to have timely access to best-practice, evidence-based assessment and care'¹⁸ and includes:

- understanding the biopsychosocial processes underpinning acute and chronic pain;
- consumer expertise included in the development of professional education materials; and
- palliative care to include well managed preventable pain, in the place of choice for patients and their families.

Ideally, any patient presenting to their GP with chronic pain being considered for treatment with opioids should be given a comprehensive pain assessment and a plan that includes a multidisciplinary approach, sound communication and early liaison with a pain management service.¹⁹

To achieve this model of care there are a range of issues to resolve that are likely to require further resources in addition to prescriber training, including:

- Limited health practitioner awareness and uptake of existing clinical guidance on the management of acute and chronic pain that includes non-pharmacological therapies. We strongly urge the Department of Health to work with key partners including the clinical colleges to provide current, clear, visible and accessible guidelines that meet a broad range of health practitioner needs.
- Understanding that pain is complex, with high variability between people. GPs require specific education and support on how to identify people at risk of developing chronic pain after acute injury (e.g. using risk assessment tools such as the Screener and Opioid Assessment for Patients in Pain) and how to develop effective care strategies.²⁰
- Revised 'clinical pathways' for the use of opioids in the acute pain setting, which could include limits on opioids prescribed on discharge from hospital, clear advice on the length of time opioids are required and information on non-pharmacological approaches.
- GPs and patients need to understand chronic pain may not be 'fixed' and treatment needs to be reframed as managing a chronic condition with coordinated care from a range of disciplines.²¹
- Greater access to and support from pain specialist services and easier referral pathways.
- A coordinated effort to support GPs in acquiring appropriate training, including a clearer understanding of what is working and what GPs need in order to provide a best-practice model of care.

Recommendation:

- Painaustralia strongly supports option 8, and the prioritisation of increasing health care professional awareness of alternatives to opioids for pain management and best-practice prescribing.
- That the Department of Health consider making pain management and prescribing education for Continuing Professional Development (CPD) programs mandatory for accreditation through the Medical Board, including identifying at-risk prescribers and supporting them to access training.
- That clinician education should not be solely be the responsibility of industry sponsors and alternative education opportunities are made available.
- That the Department of Health work with key partners including clinical colleges to provide current, clear, visible and accessible clinical guidelines that meet a broad range of needs of health practitioners.
- That the Department of Health note the best-practice model of care for chronic pain management and understand the barriers to achieving its implementation across all primary care settings.

Education and Information for Consumers

Painaustralia agrees with the TGA that 'changes in prescriber behaviour and changes in community expectations about the use of opioids in management of CNCP will have greater impact on appropriate prescription and unsanctioned use of opioids' although regulation has a role today.²²

The use and dependency on opioids is widespread, and the use of medications as 'quick fixes' is part of many people's lives. Painaustralia's recent Real Relief campaign was accessed by more than 3.3 million Australians. It raised awareness of why new access arrangements for codeine are necessary and the alternative ways to manage pain. Despite a survey of consumers showing over half supported the decision to upschedule the medication, many conveyed their strong attachment to and reliance on codeine, a lack of knowledge about its risks and alternative pain treatment options.

Knowledgeable, empowered and supported consumers are critical to improving outcomes for people with pain and addressing opioid reliance and misuse, identified as a key goal of the National Pain Strategy. These consumers can seek out appropriate advice and treatment, better understand their pain and take the first step towards adopting self-management strategies that are proven to improve activity, reduce disability and keep pain to a minimum.²³

If we are to value consumer empowerment as a key strategy to address opioid misuse, this should extend to ensuring consumers are equipped with accurate information about pain medication that reflects the Product Information (PI) approved by the TGA and equips consumers with information about dependence, addiction and the potential for misuse. Therefore, Painaustralia supports the proposed review of label warnings and revision to the Consumer Medicines Information (CMI) (option 5).

We note that some sponsors of opioid products already include CMIs as part of Risk Management Plans and the inclusion of a boxed warning on packaging is unprecedented. It is essential the right balance between safety and effective use is reached in consultation with industry and consumers.

Many people who live with chronic pain report stigma and misunderstanding in the community and amongst the medical profession, including their use of prescribed pain medications as part of their treatment. The use of language to describe opioid-associated behaviour including misuse and 'doctor shopping' can contribute to the stigmatisation.²⁴ It is important that any new regulatory approaches including labels and prescription monitoring systems should not unintentionally or intentionally punish or stigmatise people with pain and must be combined with greater access to appropriate support systems and services.

Recommendations:

- Painaustralia supports option 5 to review label warnings and revision to the Consumer Medicines Information to better support and inform consumers. This should be the subject of further consultation with consumers and industry.
- That the Department of Health note the use of regulatory approaches that target consumers must be combined with greater access to appropriate support systems and services.

Regulatory options

The Faculty of Pain Medicine states there is a 'lack of definitive evidence supporting the long-term effectiveness of opioid analgesics in people experiencing CNCP and the substantial evidence of potential harm'.²⁵ The International Association for the Study of Pain (IASP) recommends caution when prescribing opioids for chronic pain, noting there may be a role for medium-term opioid therapy in carefully selected patients, while preferring chronic pain treatment strategies that integrate behavioural and physical treatments.²⁶

Nevertheless, opioids continue to have a role in the management of chronic pain and changes to their prescribing guidelines and availability will have ramifications for many people living with pain who have been prescribed these medications, some over a long time. Further research to examine the efficacy and safety of long-term opioid therapy in CNCP including whether any sub-groups of patients experiencing CNCP have greater likelihood of ongoing therapeutic benefit and lesser likelihood of harm is also required.²⁷

Painaustralia supports the TGA's proposed reviews of current opioid regulations outlined in the consultation paper as part of a holistic and whole-of-government response to the issues arising from opioid reliance and misuse and the urgent need to address pain as a national health challenge. A key aim must be to increase awareness about the risks and efficacy of opioids, for both consumers and health professionals.

Our support is given on the basis that these are options for review and are the subject of further and formal consultation processes, which give a wide range of stakeholders the opportunity to provide comment within a reasonable time frame.

With a broad network of consumers, pain and other medical specialists, researchers, pharmacists, carers, pharmaceutical companies and allied health professionals, Painaustralia is well placed, if resourced, to facilitate and support conversations to develop the solutions to address these issues.

In relation to the options for review, Painaustralia raises the specific following points of concern:

- Excluding CNCP as an indication entirely (option 2) would be a major change to prescribing practice and would have significant impact on many people who are currently using these medications for chronic pain. Painaustralia does not support excluding CNCP in the indications for all S8 opioids due to the short-term impact of such a decision and recognition of the pharmacology of different products.
- Restrictions of highest dose products (option 3) maybe an issue in palliative care, residential aged care and in regional areas.
- Some of the options (2, 3 and 7) involve consideration of limiting prescribing of all strong opioids to classes of prescribers, such as pain medicine specialists. Painaustralia has serious concerns with this option given the limited number of pain specialists and clinics in Australia, particularly in regional areas. The potential for divergence of these limited resources from pain management strategies to prescribing, creates an unreasonable community expectation that pain specialists and clinics are the 'go-to place' for opioid prescribing and reducing the need for more widespread education across the health workforce. Painaustralia urges considerable and further consultation with clinical and population groups that would be impacted by this change, which could have a range of unintended consequences.

- There are few pharmacological alternatives to treat chronic pain on the horizon and non-pharmacological strategies remain best-practice. More research on the efficacy and safety of long-term opioid therapy as it relates to CNCP is required and worthy of greater resources and focus.
- The provision and accessibility of training, education and awareness of the clinical guidelines are critical to the realisation of prescribing reform. Partnerships with medical colleges are critical to refine the range of existing clinical guidelines and determine strategies to improve their communication and uptake.
- The oversight of prescribing pain medications should not start or end with the packaging and labelling of medications or at the primary care level. For example, the proposed national real time monitoring scheme should also include monitoring of discharge prescribing in Australian hospitals. This would involve developing a national guide and software package that public and private hospitals can quickly and easily adopt based on existing models. Patient outcomes, education for prescribers and data on opioid use post-hospital visitation are also possible in a national scheme.
- Good practice and compliance with some of the regulatory options as outlined in the consultation paper, as well as comprehensive education programs for health practitioners are already being carried out by some product sponsors. The TGA should identify where this is occurring and work with industry to identify pathways for continued quality use of medicines.
- Consideration of the interaction between opioids and other medications is critical, in relation to CMI and other changes. For example, many patients on long-term opioid therapy are co-prescribed benzodiazepines and the combination of these, potentially with other sedatives and alcohol, is associated with a further increased risk of apnoea and death.²⁸
- As mentioned above, any new regulatory approaches that focus on consumers including labels and prescription monitoring systems should not unintentionally or intentionally punish or stigmatise people with pain and must be combined with greater access to appropriate support systems and services.

Other regulatory approaches and policy considerations that may fall outside the powers of the TGA must be considered to achieve a holistic approach to address opioid medication reliance and our pain burden. These have been raised in other government-sponsored forums. The implementation of an effective national prescription monitoring system should not only reduce overdose deaths but provide pathways for those with dependence issues towards alternative treatments. It should also provide more information about why over-prescribing occurs and where.

This should also include updating the National Pharmaceutical Drug Misuse Framework for Action (2012-2015) which made many valid proposed actions to improve the quality use of medications that were not realised within the framework's timeframe, including:

- Real time prescription monitoring;
- Medication labelling reforms;
- Access to treatment for opioid dependence; and
- Exploring opportunities to improve access to non-opioid adjuvant medications for pain.

The Australian Government is also urged to revisit the recommendations of the 2015 Opioids Roundtable convened by the Department of Health to improve patient care by reducing administration burden for health professionals regarding PBS listed opioids. In addition, recommendations to increase access and awareness of best-practice pain management, were recommended including:

- All patients with CNCP should undergo a trial treatment period of 1-3 months to assess their responsiveness to opioid therapy, noting the current 12-month review is ineffective;
- Data is needed on the effectiveness of opioids to inform best-practice and support evidence-based decision making;
- An online authority system to reduce regulatory burden to encourage quality use of opioids; and
- Real-time prescription monitoring.

The interactions between the decisions of the TGA and the operation of the Pharmaceutical Benefits Scheme (PBS) could create additional regulatory impacts on the availability and cost of medications.

The harmonisation of implementation of regulation between jurisdictions remains a key issue and should be a focus to achieve greater consistency for consumers and prescribers no matter what their location might be.

Recommendations:

- Painaustralia supports a review of regulatory options for opioid prescribing as part of a holistic and whole-of-government response to opioid reliance and misuse and the need to address pain as a national health challenge.
- Support for this review is contingent on further and formal consultation processes with a wide range of stakeholders, with a focus on unintended consequences, and Painaustralia can take an active role in facilitating these discussions through its network.
- That the Department of Health note any changes to the prescribing of opioids will directly affect many people living with pain who currently use these medications and health practitioners over the short, medium and long terms.
- That the Department of Health carefully consider reform options that have been previously raised and prioritise the implementation of an effective national prescription monitoring system.

Conclusion

To meet the health challenges of opioid misuse and the rising pain burden, Australia needs a holistic and cross-portfolio strategy that has the support and engagement of a wide range of stakeholders.

This will be beyond the remit of the TGA and must encompass a wide range of policy levers.

We welcome this step towards identifying the solutions and we are encouraged by the strong emphasis on education, training and awareness. We support further review and investigation of the regulatory arrangements that affect opioid prescribing on the basis they are subject to considerable further consultation and discussion.

Painaustralia welcomes any opportunity to work with government to address the issues outlined in our submission and develop the sustainable solutions necessary to address this costly health challenge.

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