



**Public Health Association**  
AUSTRALIA

# **Public Health Association of Australia submission on Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response**

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# Introduction

## The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia. The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

## Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

## Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

# Preamble

PHAA welcomes the opportunity to provide input to the proposed regulatory response to the use and misuse of prescription strong (Schedule 8) opioids in Australia. The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. The Australian Government, in collaboration with the States/Territories, should provide a comprehensive national cross-government framework on promoting a healthy ecosystem and reducing social and health inequities. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

# PHAA Response to the consultation paper

## Schedule 8 medications and their use and misuse in Australia

Prescription opioid medications are currently divided into Schedule 4 (S4 – prescription only medicines) and Schedule 8 (S8 – controlled drugs). Schedule 8 includes: buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone, talpentadol, and pethidine.

There are complex factors which contribute to opioid misuse, requiring a complex set of measures to address the problem. The increase in recognition of the under-treatment of pain, the increased prevalence of chronic pain due to the ageing population, the introduction of sustained-release opioid preparations (e.g. OxyContin), longer cancer survival periods, undertreated mental health issues and aggressive promotion of particular medications by pharmaceutical companies are all factors likely to have contributed to the increase in opioid prescriptions in recent decades.<sup>1,2</sup> This is reflected in a 15-fold increase (500,568 to 7,495,648) in prescriptions for PBS-listed opioids (both S4 and S8) between 1992 and 2012.<sup>3</sup>

There is a resulting spectrum of opioid misusers, from those who unintentionally become dependent while taking prescribed opioids as directed, through to those who intentionally misuse prescription opioids. Not all prescribing practices in this context may be evidence-based. As noted in the consultation paper, where other, more appropriate, treatments are available but under-used ('indication creep'), the problem compounds at the lower end of the spectrum. A study of clients of drug treatment services has found that misused prescription opioids such as morphine, oxycodone and methadone liquid were usually obtained from non-prescribed sources including from friends or dealers.<sup>4</sup> Common sharing and on-selling of prescription opioids may limit the impact of regulatory changes for this population who intentionally misuse.

The public health response to this issue in Australia was outlined in the National Pharmaceutical Drug Misuse Framework for Action with guidelines for appropriate opioid use, a prescription monitoring program and medication-assisted treatment.<sup>5</sup> Commonwealth funding for a national real time prescription monitoring system of controlled medicines including S8 opioids was announced on 28 July 2017.<sup>6</sup> This system would have the advantage of monitoring not only the patterns of filled prescriptions for individual patients, but patterns of prescribing for individual medical practitioners, thus enabling inappropriate practices of either to be identified.<sup>1</sup> There are potential concerns, however, to ensure that the monitoring does not reduce clinically appropriate prescribing, or simply shift prescribing to lower level medications not included in the monitoring system.<sup>7</sup>

Regulatory responses must take this context into account in their attempts to reduce opioid misuse.

## Option 1: Consider the pack sizes for Schedule 8 opioids

Option 1 would require sponsors to register and make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28 day) for treatment of people with chronic pain due to malignancy.

PHAA strongly supports this option as being a sensible prevention measure. Where patients have acute pain arising from, for example, minor surgery, and they are likely to require strong pain medication for only a few days, appropriate packs should be available. With risks of long-term use increasing after as little as 5 days taking prescription opioids,<sup>8</sup> patients should not be prescribed more than they are likely to require. However, there should be a clear effort to ensure reasonable access for people who are in palliative care.

## **Option 2: Consider a review of the indications for strong opioids**

Option 2 would involve a TGA review of indications for the S8 opioids and aligning them to current clinical guidelines for appropriate prescribing.

PHAA supports this option as a prevention measure through ensuring the clinical guidelines are based on current evidence, and include known effects of differences in pharmacology and for cancer pain compared with non-cancer pain. Such reviews should be a routine part of quality improvement processes.

## **Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing**

Option 3 would review the place of the higher dose S8 opioid products in the management of chronic cancer and non-cancer pain and whether certain high dose products should continue to be registered. This would consider whether specific controls, such as approval to prescribe through states and territories or the PBS should be introduced.

PHAA supports in principle the reduction of the supply of the highest dose opioid products to patients who do not require them, and for whom suitable alternatives are available. However, where these products may be clinically indicated for some patients, they should be both available and accessible. This would need careful consideration, especially for patients in regional and remote areas.

## **Option 4: Strengthening Risk Management Plans for opioid products**

Option 4 would review current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.

The PHAA does not have a view on this option.

## **Option 5: Review of label warnings and revision to the Consumer Medicines Information**

Option 5 would place warnings on the packaging of opioid products identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of non-cancer pain, noting that the complexity of appropriate management of chronic non-cancer pain needs to be recognised. The CMI would also be reviewed to provide greater emphasis on risks of dependence, especially on those associated with high doses.

PHAA supports the inclusion of better information for patients regarding the risks and benefits of their medication. The provision of consumer warning labels and information is a well-established public health strategy. Even when patients are fully informed by the Medical Practitioner at the time of prescribing, and this information is reinforced by the Pharmacist at the time of dispensing, it is essential that patients are able to access accurate information about their medications at any time.

## **Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes**

Option 6 would provide priority review to new chemical entities that are viable alternatives to opioids for pain relief and also expedite the review of smaller pack sizes and/or abuse-deterrent formulations and products that can be used to negate the effect of opioids.

The PHAA does not have a view on this option.



## **Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids**

Option 7 uses powers under medicines scheduling to include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels.

The PHAA supports label warning statements, but does not have a view on whether the powers under medicines scheduling is the appropriate mechanism for achieving this.

## **Option 8: Increase health care professional awareness of alternatives to opioids**

Option 8 would have existing clinical guidelines for the management of acute and chronic pain provide advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain. While these are available there may be limited health practitioner awareness and uptake.

PHAA supports an increase in the ready availability and accessibility of evidence for health professionals about the risks, benefits and appropriate use of opioids, including better defined clinical pathways.

# **Conclusion**

PHAA supports the broad direction of the proposed regulatory options for prescription strong (Schedule 8) opioids in Australia. We are particularly keen that the following points are highlighted:

- There is a spectrum of misuse of opioids and regulation may be a useful method of addressing unintentional dependence and indication creep
- There should be minimal restriction for use by people who are in palliative care
- Regulatory responses may be less useful for intentional opioid misuse
- The provision of accurate information to both patients and prescribers is a useful prevention measure
- The availability of appropriately sized packs of medication, taking into account evidence about how quickly people may become dependent, is strongly supported

The PHAA appreciates the opportunity to make this submission and the opportunity to contribute to the reduction of misuse of opioids in Australia.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.



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