



CATAG submission

TGA Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

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The Council of Australian Therapeutic Advisory Groups (CATAG) is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents.

CATAG aims to standardise and improve medicines use primarily (but not exclusively) in the hospital sector across Australia through information sharing, advice and advocacy activities.

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CONTEXT

The Council of Australian Therapeutic Advisory Groups (CATAG) believes there is a need for a multi-faceted strategy to address the misuse of prescription opioids. The regulation of opioids through prescription and supply is one instrument, which will contribute to addressing widespread misuse.

REGULATION OF OPIOIDS - OPTIONS

Opening remarks

It is widely acknowledged the misuse of opioids is of growing concern in Australia and has been noted internationally as reaching a crisis point. An impact assessment of the proposed regulatory changes needs to be undertaken prior to the implementation of any changes in order to identify unintended consequences. Post implementation evaluation of the desired outcomes should be measured to determine success. Consumers are the end users of medicines and therefore any change in regulation through the implementation of regulatory levers to manage prescription and supply should consider genuine consumer needs and the impact it would have upon their quality of life and safe use of medicines. Any changes made should have positive impacts on how consumers understand, manage or utilise their medicines.

1. Pack sizes for Schedule 8 opioids

CATAG supports this approach

The availability of smaller pack sizes for the treatment of patients with acute pain is an essential change, which needs to be made. It would be beneficial if these smaller pack sizes were also PBS listed, as this would have the potential to influence prescribing to a greater extent. Smaller pack sizes would also enable earlier review of patients with acute pain and medication effectiveness.

Higher doses and larger pack sizes should remain available for patients with chronic cancer pain and/or use in palliative care, to be prescribed by the relevant specialist, possibly using a streamlined authority process (see Option 3). Any change should not disadvantage patients who may require higher doses and larger quantities to adequately manage their pain.

2. A review of the indications for strong opioids

CATAG supports this approach, however other regulatory interventions may have a greater impact. As Option 2 is a passive intervention, there would need to be some alignment with the PBS listing to be more effective. Consistency of indications across all 'strong opioid' products would provide clarity for clinicians and patients. Changes to the Product Information would also mean adjusting the Consumer Medication Information. Aligning the indications to current clinical guidelines would

require significant consultation and time in addition to a timeline for review. Guidelines are working documents and require updates to reflect developments in evidence and best practice.

Consideration needs to be given to instances where a product is routinely used 'off label' as accepted standard practice; how this would be addressed is currently unclear.

The product information should also include information and evidence discussing the efficacy of opioids in non-cancer pain and greater reference to risk of harm and harm minimisation

3. High dose products remain on the market or restricted to specialist/authority prescribing ***CATAG supports this option***

This option needs significantly more detail. Higher dose products could be initiated by a specialist, whereby the specialist has oversight of the patient, however where continuation of a product is required this could be continued by a GP. The patient should be reviewed by the specialist every 6 months and treatment plans communicated to the patient's GP. When prescribing at the recommendation of a specialist, GPs must confirm that the prescription is needed, appropriate for the patient and that the prescription of medicines is within the scope of their individual professional competence. GPs should also establish regular communication with the patient's specialist prescriber when prescribing at their recommendation. Those in rural and remote Australia have reduced accessibility to appropriate specialist care than their urban counterparts and this would need to be considered when implementing restrictions to opiate prescribing to only specialists. Implementing an authority to prescribe, where prescribers need to apply for a PBS authority may cause prescribers to be more conservative when increasing patients' doses.

The legislation in the various jurisdictions varies. Currently NSW legislation requires a prescriber to obtain an authority from the Ministry of Health to prescribe a drug of addiction for 1) a patient who is considered 'drug dependent' or 2) in the case of a non-drug dependent person, the prescription of any injectable or inhaled formulation of any drug of addiction, or the prescription of the opioids, buprenorphine (except transdermal preparations), hydromorphone and methadone beyond 8 weeks. Victorian legislation requires practitioners to apply for a permit when prescribing schedule 8 treatments for a period greater than 8 weeks. The differences in legislation need to be accounted for when considering introducing new controls. State and territory legislation should be examined to ensure any regulatory changes improve the intent of current legislation and safeguard patients, prescribers, pharmacists and nurses. There would be value in evaluating jurisdictional applications for authority to prescribe in order to understand if there are mechanisms in place to trigger reviews or alerts for health departments and prescribers and provide prescribers with supports to manage patients appropriately.

There is perversity in the current system, opioids are able to be readily prescribed by all doctors without restrictions to their registration; however, in order for doctors to prescribe treatments to address opiate addiction, additional credentialing is required.

4. Risk management plans

CATAG supports this option

The implementation of risk management plans (RMP) as a strategy to mitigate the risks of harm associated with opioid use are welcomed, however they need to extend beyond the traditional pharmacovigilance and education activities. A suggested novel option for an opioid RMP is the provision of naloxone when high dose opioids are prescribed, how this would be operationalized needs further exploration. This would significantly reduce the risk of harm. It is well-documented prescription opioids have been associated with a high risk of overdose death and the provision of naloxone would serve to mitigate this risk.

In general RMPs for high-risk medicines should have greater scrutiny and oversight. High-risk medicines include those that have an increased risk of causing significant patient harm or death if they are misused or used in error¹. In the acute sector in Australia, the 'APINCH' acronym and classification is widely used to assist clinicians focus on a group of medicines known to be associated with high potential for medication-related harm². For these medicines consideration should be given to the development and implementation of an overarching risk management plan for the drug class, such as opioids instead of individual drug RMPs. This would ensure consistency of messaging and more effective medicine management.

5. Review of label warning and revision to the Consumers Medicines Information

CATAG supports this option

CATAG recommends a review of the efficacy of ancillary labelling is undertaken: are they an effective method of communication of risk of harm, do consumers take notice of ancillary labels and do consumers take any further action as a result of reading this information? Changes to the CMIs of opioids are welcomed to provide greater emphasis on the risk of dependence associated with opioid use and methods that mitigate this risk; the inclusion of information regarding where to seek help if consumers are concerned about dependence would also have added benefits.

A review of CMIs in general would be welcomed, as they are not user-friendly for consumers or for health professionals using them as a medication counselling aid. It is well documented Australia's overall health literacy is poor and there has been substantial Australian research that investigates written medicine information to consumers that would assist development of more user-friendly CMI.

¹ 1 Cohen MR. Medication Errors, 2nd edition. Washington DC. American Pharmacists Association; 2007

² 3 Clinical Excellence Commission (CEC). High-Risk Medicines A PINCH. <http://www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/high-risk-medicines/A-PINCH> (accessed September 2017).

6. Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

CATAG supports this option

CATAG supports expedited TGA reviews of opioid antidotes. The current challenges for consumers and their carers with the available antidote formulations is the way in which naloxone is delivered. Many people are not comfortable with delivering medication through a syringe. Ampoules are more difficult for carers to manipulate and draw up to administer naloxone. There is a FDA-registered intranasal product whose formulation would be advantageous due to its usability without prior training. Any TGA review of such a product should be incentivised and expedited to allow for widespread availability.

CATAG would support expedited reviews of improved products for pain relief if they are products where the risk of harm is truly reduced (rather than delayed or ultimately non-existent). For example, the introduction of a new formulation of OxyContin Reformulated Modified Release tablets™ does not appear to have reduced risk of harm despite initial claims that it would do so.

7. Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids

CATAG supports this option

CATAG supports an amendment to the poisons schedule whereby prescribers will be required to undertake an approved training/credentialing course in order to continue the prescription of strong opioids. There are current education requirements to prescribe opiate dependency products in the States and territories. For example, in NSW, prescribers of methadone or buprenorphine to more than 5 patients, must successfully complete a training program. It seems reasonable that, if further education is required to treat addiction, the same type of requirements should be applied when treating a patient with a medicine, which can cause significant addiction in the medium to long term.

Amendments to legislation allow for restrictions to be imposed that cannot be circumvented. In contrast, PBS restrictions can be circumvented particularly when products are relatively low cost (such as opioids) as these may be prescribed as non-PBS private scripts. A PBS restriction would only be a barrier to lower income earners or those reaching the PBS safety-net.

8. Increase health care professional awareness of alternatives to opioids in the management of chronic pain

CATAG supports this option but recognises its limited impact as a sole strategy for harm minimisation

Health professional awareness and education has been mentioned in a number of the options suggested. This option has no regulatory lever and although it would need to accompany other strategies, an education program that solely raises professional awareness alone would be ineffective. In fact, it is likely awareness on the part of health care professionals is not an issue given the media coverage of the opioid crisis. Other barriers to health care professional adoption of best practice recommendations need to be explored, identified and addressed.

Education used as the sole intervention is well known to be relatively ineffective in changing behaviors. The evidence demonstrates that, while education may be part of a successful multi-faceted strategy for behavior change, indeed a necessary part, as a lone strategy however, it is ineffective, costly for its limited impact and is placed on the lowest rung in the hierarchy of intervention effectiveness.ⁱ

Passively providing information (whether specific or non-specific) through websites is not appropriate nor a sufficient mechanism for improving prescribing. Although the information on the NPS MedicineWise website is valuable, anecdotally, there are gaps in consumers' awareness of the NPS MedicineWise website as well as competition for consumers' attention. Furthermore, although healthcare providers may become familiar with NPS MedicineWise resources during undergraduate and early career training, time constraints and competing priorities limit HPs' further engagement with new and/or changed information. In addition, while NPS MedicineWise conducts regular education visits with general practitioners (GPs) and is thus recognized as providing high quality information on medicines to these HPs. More should be done at the transfer of care/discharge to inform GPs about the cessation of opioids initiated for acute pain when patients are discharged from hospitals following surgery or injury. There is a role for the development of health pathways through local health districts and primary health networks. NPS MedicineWise historically has had much less interactions with medical specialists and thus is less well known to this group who are likely to be the key prescribers in the initiation of opioids during hospitalization and at discharge. Therefore other key education providers such as the RACP and the specialist colleges should be engaged.

Possible role of PBAC

The PBAC should consider incorporating the costs of harm into the economic models when considering introduction of smaller pack sizes or new medicines with addiction potential. The cost of opiate dependence is significant, and potentially this cost could be offset.

SUMMARY

CATAG recognises the value in a multifaceted approach to this complex problem and therefore has provided comment on each of the options proposed. CATAG considers some options proposed will be more effective at mitigating the impacts of opioid misuse; these include options 1, 3 and 6. As highlighted in the consultation paper, there are areas that are not regulatory matters per se, but will support behaviour change in combination with other strategies. The cost of potential harm from opioids needs to be factored into registered products or eligibility for PBS subsidisation. Risk management plans should incorporate more monitoring and activities than passive pharmacovigilance strategies.

ⁱ Cafazzo JA and St-Cyr O. From Discovery to Design: The Evolution of human Factors in healthcare. *Healthcare Quarterly* 2012; 15:24-29.