

2 March 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Prescription strong (schedule 8) opioid use and misuse in Australia – options for a regulatory response

NPS MedicineWise welcomes the opportunity to provide comments and feedback on *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response*. We consider this to be a vital piece of work, acknowledging the issues and regulatory responses are inherently complex.

NPS MedicineWise supports the exploration of regulatory options to help address excessive or inappropriate use of opioids. We support measures that improve the safe, effective, wise and judicious use of medicines and treatments.

We agree with the acknowledgment in the discussion paper that sustained prevention of harm and improvement in outcomes for Australians with pain and addiction will require a much broader set of measures outside the options presented in this paper. Nevertheless, we consider a number of the regulatory options proposed are appropriate to help deal with this challenge.

Smaller pack sizes and review of indications

NPS MedicineWise believes smaller pack sizes for S8 opioids depending on the indication should be explored. We know from international evidence that duration of treatment rather than dose is more strongly associated with opioid misuse after surgery.¹

We acknowledge that for some acute pain conditions, a short course of pain relief with opioids is appropriate. Current pack sizes, which align with PBS approved quantities, can make it difficult for prescribers to prescribe a quantity appropriate for short-term pain relief. This is particularly salient for patients requiring immediate pain relief after discharge from hospital or after a dental procedure.

We believe that a review of pack sizes should be clearly dependent on the indication. In conditions where prolonged opioid use is appropriate, for instance in opiate responsive chronic pain related to malignancy, prescribers should have the ability to easily prescribe appropriate quantities to as to not disadvantage patients.

Furthermore, we recognise that the impact of smaller pack sizes would be strengthened – and might be dependent – on harmonisation with ARTG indications and PBS listing. We would therefore recommend that consideration of option 1 be in tandem with option 2: a review of the indications for strong opioids.

We also suggest that work could be done with medical software industry groups to encourage electronic prescribing systems to default to the lowest pack size for schedule 8 opioids. We believe better use of digitally enabled prescribing and dispensing systems can offer more contemporary checks and balances to support more appropriate use of schedule 8 drugs. This is especially important if PBS authorities for

increased quantities and/or repeats for schedule 8 drugs will soon be e-health enabled to be less administratively burdensome for clinicians while capturing more and better data the patient and prescriber.

Restricting prescribing rights

NPS MedicineWise believes prescribers should receive appropriate training and be able to demonstrate competency to prescribe high-risk medicines. However, it is important that any change to regulations which restrict provider rights to prescribing opioids does not reduce patients' appropriate access to general practice pain management support, noting:

- ▷ It can be difficult for people to gain quick access to pain specialist services due to long waiting lists for public clinics and services and cost barriers to accessing private services.
- ▷ Despite guideline recommendations emphasising the limited role for opioids in chronic pain management, in practice many patients with chronic pain do have opioids commenced or recommended by pain specialist services and continued under their direction—with an expectation that general practitioners will continue prescribing these between specialist service appointments.

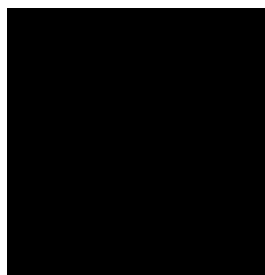
Improving education and awareness

We note a number of measures for consideration focus on increased provision of education to health practitioners. As a national provider of education and behaviour change initiatives on quality use of medicines we believe enhancing health professional knowledge plays a crucial role in improving patient outcomes.

- ▷ We agree with the proposal that pharmaceutical company sponsors should support education as part of a drug's risk management plan to help ensure prescribers receive up-to-date and accurate education on changes in therapy. However, we would stress that sponsor-funded or provided education must, in the first instance, provide prescribers with balanced information on a drug in the context of its place in therapy and compared to other medicines and non-drug treatments. We believe an independent organisation, like NPS MedicineWise, could be tasked with helping sponsors to build independent and trustworthy education.
- ▷ NPS MedicineWise has a range of online education modules to help students and prescribers understand the role of opioids in pain management. These could be leveraged, along with other opioid educational resources already in existence, to support consistent and best practice use of opioids.

We are very happy to provide any additional information that may be required. Please contact Brad Gellert, External Relations and Policy Adviser on [REDACTED].

Yours sincerely



1. Brat GA, Agniel D, Beam A, Yorkgitis B, Bicket M, Homer M, et al. Postsurgical prescriptions for opioid naïve patients and association with overdose and misuse: retrospective cohort study. *BMJ* 2018; 360: j5790. Available from: <http://www.bmj.com/content/360/bmj.j5790>