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**Comments on options for a regulatory response to the potential misuse of prescribed Schedule 8 (S8) opioids in Australia.**

The NSW Poisons Information Centre (NSWPIC) provides a phone-based advice service on suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

**Option 1: Consider the pack sizes for strong (S8) opioids**

The NSWPIC supports reduction in pack size of strong opioids to a pack size of 3 days supply for use in management of acute pain. Reducing access to medications in quantities greater than is immediately required will minimise risk of both unintentional exposures and deliberate self-poisoning. Following reduction in pack size of paracetamol in the UK there was a 43% reduction in deaths due to overdose with paracetamol.<sup>1</sup>

**Option 2: Consider a review of the indications for strong (S8) opioids**

The NSWPIC supports a review of the indications for strong opioids and limitations of their indication for management of chronic pain in non-cancer patients.

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

The NSWPIC received over 1500 calls regarding exposures to strong opioids in 2017. Of these, 75% required medical attention. Higher dose opioid products are even more likely to need medical assessment particularly in therapeutic errors or accidental exposures in opioid naïve patients.

**Option 4: Strengthening of the Risk Management Plans for opioid products**

The NSWPIC supports a review and strengthening of Risk Management Plans for strong opioids. Data collected by the four Australian Poisons Centres provides a valuable resource in assessing the level and extent of risk which currently exists, as well as being able to provide feedback on effectiveness of risk minimisation measures which may be implemented for strong opioids. Similar monitoring systems which exist in the US (RADARS) have provided useful information in the trends of therapeutic and illicit opioid use and misuse.<sup>2</sup>

The NSWPIC can provide data which will assist to evaluate comparative misuse potential within the opioid class of medication. A study regarding misuse potential of Tapentadol has already been approved and will commence shortly.<sup>3</sup>

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

The NSWPIC supports a review of label warnings and revision to the consumer medicines information. Educating patients about the potential risks of opioid use is an important component in minimising misuse and promoting safe use of medicines. Changes to labelling of paracetamol packaging requiring warnings of potential liver damage did result in an increased awareness of dangers associated with excessive use of paracetamol, and was associated with an increase in calls relating to paracetamol made to the NSWPIC.

Year	Calls to the NSW PIC regarding Paracetamol
2012	5283
2013	5316
2014	5635
2015	6113

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

The NSWPIC would recommend caution in expediting approval for new non-opioid pain relief products, particularly gabapentinoids which have abuse potential.<sup>4</sup>

#### **Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids (this could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels).**

The NSWPIC provides in principle support of specialist prescribing of strong and high dose opioids.

#### **Option 8: Increase health professional awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain.**

The NSWPIC supports increased awareness of alternatives to opioids in both health professionals and patients in the management of chronic pain.

## References

1. Hawton K, Bergen H, Simkin S, et al. Long term effect of reduced pack sizes of paracetamol on poisoning deaths and liver transplant activity in England and Wales: interrupted time series analyses. *BMJ* 2013; 346 :f403
2. Dart RC, Surratt HL, Cicero TJ, et al. Trends in opioid analgesic abuse and mortality in the United States. *N Engl J Med* 2015;372:241-248
3. Peacock A, Larance B, Farrell M, et al. Opioid Use and Harms Associated with a Sustained-Released Tapentadol Formulation: A Post-Marketing Study Protocol. *BMJ Open* 2018; accepted manuscript in press
4. Evoy KE, Morrison MD, Saklad SR. Abuse and Misuse of Pregabalin and Gabapentin. *Drugs* 2017; 77, 403–426.