

## **TGA Consultation on Prescription strong (Schedule 8) opioid use and misuse in Australia**

### **Submission by the Pharmacy Council of New South Wales**

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The Pharmacy Council of New South Wales is the statutory body responsible, in partnership with the Health Care Complaints Commission, for managing complaints and notifications related to the conduct, performance or health of pharmacists practising in NSW and NSW pharmacy students. The Council is also responsible for the approval and registration of pharmacy premises in NSW.

The Pharmacy Council has considered the TGA's *Prescription strong (Schedule 8) opioid use and misuse in Australia* consultation paper and provides the following comments:

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

The Council supports the proposal to require sponsors to register and make available for supply:

- (a) smaller (eg 3 days maximum) pack sizes, for treatment of patients with acute pain, where these changes do not put an unfair cost burden on patients; and
- (b) suitable pack sizes (eg 14 or 28 days) for treatment of patients with chronic pain from malignancy provided that access to treatment for these patients is not reduced.

We agree that these changes may be able to be implemented using the TGA's powers with regard to the scheduling of medicines, the registration of medicines, or a combination of both the scheduling and registration processes.

Further, consideration should be given to providing fair remuneration to pharmacists should the prescribed treatment require original packs to be broken for dispensing the prescribed quantity.

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

The Council supports the proposal. It appears logical and a requirement of best practice that indications for the S8 opioids should be aligned with the current clinical guidelines for appropriate prescribing of these products. Therefore it makes abundant sense for the TGA to review the indications for S8 opioids with the view to amending them to align with current clinical guidelines where appropriate.

An Opiate Care Plan should be mandatory for all opiate prescriptions for chronic pain not arising from a malignancy.

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

The Council supports reviewing:

- (a) the place of higher dose S8 opioid products in the management of chronic cancer and non-cancer pain; and
- (b) whether certain high dose products should continue to be registered,

as long as physicians seeking to give relief to patients with chronic pain from malignancy continue to have available to them appropriate opioid treatment options.

Furthermore, the Council supports consideration of the merits of introducing specific controls (eg approval to prescribe through prescribing rights, or the PBS).

The Council supports the TGA undertaking a safety review of the benefit/risk ratio for higher dose S8 opioid products and opioid tolerance.

The Council supports specialist-only / authority prescribing regardless of PBS reimbursement. However, in the implementation of this measure, consideration should be given to improving (or as a minimum retaining) access for patients to approved prescribers, including afterhours and weekend access. Consideration should also be given to the impact on hospital outpatients from implementation of increased restrictions.

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

The Council supports the proposal. The formulation of risk management plans must include a starting point of lower strengths and smaller pack sizes.

We support increased education of health professionals and also the users of these medications.

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

The Council is of the view that these options need to identify opioid combinations which increase the risk of side effects and tolerance at lower doses when more than one opioid product is used.

The Council agrees that S4 opioids such as tramadol should also be considered.

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

The Council supports this proposal.

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

The Council supports changes to the scheduling to provide additional regulatory control. For example, if Option 1 regarding different pack sizes was implemented, there could be less prescriber restriction in respect of smaller pack sizes than applies to larger pack sizes. The larger size could be restricted to specialists; or by authority for patients residing in remote areas.

When reviewing labelling and the use of warnings, the Council recommends considering whether increased warnings will have an undesired effect and encourage overuse rather than deterrence.

#### **Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain**

The Council supports this proposal. The Council also recommends including allied health non pharmacological options such as massage, stretching, pilates and physiotherapy along with the guidelines for prescribing.

The Council acknowledges there is merit in seeking to increase awareness via an education module however is of the view that this may be difficult to implement or enforce, in light of the experience with the guidelines on prescribing of antibiotics.

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