My name is [redacted].

I am a specialist anaesthetist and pain physician. I have also in the past been Director of the Acute Pain Service at the Royal Hobart Hospital. I therefore have experience in the use of opioids in both acute and chronic settings. I welcome the opportunity to comment on some of the Regulatory options which are being currently considered.

Option 1: Consider the pack size for Schedule 8 opioids.

The idea of opioids being prescribed in the acute setting based on package size rather than a clinical indication is ridiculous. There is ample evidence, both in the literature and in my own experience of opioids being left over and used by family members or friends for various non-supervised reasons.

Excessive use of opioids for acute pain may contribute to dependence.

It is my practice to prescribe the number of tablets of oxycodone I believe the patient will need after surgery rather than the convenient 20 pack size.

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

There are 2 categories of patients to consider: the first group includes who already are on very high doses of opioids and we need to remember this is an iatrogenic problem ie it was created by the medical profession. Although all efforts should be made to encourage these patients to wean these high doses, in practice this is very difficult and maybe we should accept the status quo.

However, there should be an emphasis on future patients with chronic non-cancer patients not ending up on high doses. It would be disastrous if we continued to repeat our past mistakes.

I don't believe there is a need for the TGA to undertake a review of the benefit/risk ratio as there is conclusive evidence that the harms outdo the benefits for opioids in chronic non-cancer pain.

I would encourage the TGA to have a uniform policy applied to all states which placed a ceiling on opioid doses in chronic non-cancer pain. Exceptions to this rule would require a pain specialist opinion.

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

Currently tramadol is schedule at Schedule 4 and tapentadol as Schedule 8. This seems a little inconsistent. There is very little mention of tapentadol in the draft document.

I suspect that tapentadol is in Schedule 8 because clinical trials have demonstrated an equianalgesic ratio of 1:2.5 for conversion from morphine to tapentadol.

However, tapentadol derives its analgesia from two actions; opioid receptor agonism and noradrenaline reuptake inhibition. The affinity of tapentadol to the mu-receptor is 1:18 compared to morphine which is a lot less than the 1:2.5 equianalgesic ratio. This emphasizes the contribution of the noradrenaline uptake component which makes tapentadol more than just another opioid.

Most of the chronic pain I see is mixed pain ie there are both nociceptive and neuropathic components which make tapentadol a much better option than a pure opioid. The role for opioids in neuropathic pain is very limited.

My understanding is that the abuse and diversion potential for tapentadol is very low.

I am not sure if having tapentadol as a Schedule 8 category alongside traditional opioid is appropriate as there are clear differences and advantages.

There are two ways to tackle this: education of the various prescribers about the differences between tapentadol and opioids or consideration of the scheduling of tapentadol as a Schedule 4 medication.