RESPONSE TO TGA CONSULTATION PAPER

NSW ACI PAIN MANAGEMENT NETWORK

Option 1: Consider the pack sizes for Schedule 8 opioids

Agree with increasing the availability of smaller pack sizes. We agree that this would help reduce the problem of people being prescribed more strong opioids than necessary in the acute pain and postoperative setting. This should include oral liquid formulations dispensed to children for management of severe acute pain, complex post-trauma and post-operative pain.

Agree with changes to PBS listing to include acute postoperative pain and cancer-related pain. We agree that non-inclusion of these indications currently is not consistent with use.

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

Agree with reviewing the indications for strong opioids.

However, we would disagree with moving to exclude chronic non-cancer pain as an indication for opioid prescription entirely for either adults or children. This would be a major change in current prescribing practice and would have major ramifications particularly for the large number of people currently using opioid medications. Indeed, in paediatrics, the WHO expanded the indications for use of their latest pharmacological treatment guideline to include use of opioids for persisting pain in children with medical illnesses (www.who.int/medicines/areas/quality_safety/guide_perspainchild/en/).

We would also disagree with limiting prescribing of all strong opioids to a certain class of prescribers such as pain medicine physicians.

There are several issues of concern with this proposal:

- It would mean that pain clinics/pain medicine physicians could be seen as "the place/person that will approve my opioids". This creates unrealistic expectations and potentially frustration and anger where this expectation is not met.
- It may avoid the need to educate or put in place other measures. It may be easier for the local doctor to shift responsibility to another prescriber than to take measures at the primary care level.
- There are not currently enough resources in the system for pain medicine physicians and pain clinics to handle the workload that this would create.

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

We agree with greater restrictions on the prescribing of high dose opioid formulations. There is a demonstrated substantial risk with use of high and even moderate doses of opioids (> 50 mg/day oMEDD) and even greater risk at > 100mg/day oMEDD. There appears to be a strong argument therefore that opioids **at or above** 90mg oMEDD should not be PBS indicated for the treatment of chronic pain. However, we would agree that opioids ≥ 90 mg oMEDD may have a role in palliative care. W**e would agree with the suggestion that high dose (≥ 90 mg oMEDD) opioid formulations be restricted to the treatment of cancer-related pain and severe pain in the context of other life-**

limiting illnesses and/or pain medicine and palliative care providers or GPs with the approval of a palliative care or pain medicine physician.

We agree that fentanyl is of major concern because of the demonstrated increased risk of accidental overdose and diversion and **would agree with restricting the use of fentanyl in the treatment of chronic pain**. If the option above is implemented, that would restrict use to 12mcg and 25 mcg patches in the treatment of chronic pain. However, given the increased risk and the availability of other options, **we feel that there is a good argument to restrict the use of fentanyl to the palliative care setting and the treatment of cancer-related pain and severe pain in the context of other life-limiting illnesses in adults and children**. This would also be simpler to implement.

We agree with making naloxone more widely available. Given the demonstrated increased risk of accidental overdose above 50mg/day oMEDD, **we would recommend that a person taking ≥60mg/day oMEDD and those likely to be in their immediate vicinity such as relatives, partners and carers should be educated regarding their risk of accidental overdose and signs to indicate the need for intervention and be provided with access to naloxone with instructions on use**. Education should include information regarding the risk of severe pain and withdrawal symptoms in people who are opioid dependent, particularly in the palliative care setting. Furthermore, education should be tailored to the person's household, with detailed information about safe storage, risk and management of overdose should it be accessible to / ingested by children or household members with depression and suicide risk.

Option 4: Strengthening Risk Management Plans for opioid products

Agree with strengthening risk management plans including improving education for health professionals and people living with chronic pain. The NSW ACI Pain Management Network has developed a website with extensive resources including education regarding opioid use and this could contribute to or form part of available educational resources. With the evidence to support the benefits of real-time prescribing we also support the introduction of this initiative across all states.

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

Agree with strengthening warnings and providing more information on labels and consumer medicines information. This would help to strengthen the message and provide support to prescribers in communicating the risks of opioid use. Concerns about deterring appropriate use could be addressed by clearly communicating the dose-related nature of the risk which would allow for use of low to moderate doses but deter use of high doses which carry higher risk.

Agree with consumer warnings to advise that opioids are not generally recommended for long-term use in chronic non-cancer pain, and acute treatment should be limited to a few days and then pain managed by non-opioid medication. The CMI of strong opioids should also align with the PI to include information about the risks of overdose, dependence and addiction associated with opioid use. Also recommend including risk if inappropriately administered to persons other than the person named on the prescription.

Agree with barcoding or QR coding to reduce risk of diversion.

Support improvements to PIs encouraging return of unused medicines.

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

Agree with priority review of new chemical alternatives to opioids.

Agree with the review of smaller pack sizes and/or abuse deterrent formulations

Agree with the rapid review of opioid antidotes or devices

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

Agree with some controls of prescribing for particular populations or classes of medical practitioners.

As mentioned, there is now clear evidence of increased risk with daily opioid doses of >50 mg/day oMEDD and lack of evidence of effectiveness in treating chronic pain.

Therefore, as above in Option 3, we would **agree that there is a strong rationale to limit prescribing of high dose opioid formulations (≥90 mg oMEDD) to the treatment of cancer-related pain and severe pain in the context of other life-limiting illnesses**. Given the evidence for lack of effectiveness in chronic pain and high risk, we would see no reason for these formulations to be used in chronic non-cancer pain outside those contexts.

We would **disagree with including chronic non-cancer pain as an indication for high dose opioids outside the palliative care context**.

If limited to classes of practitioners, **we would agree with limiting prescription of high dose opioid formulations to pain medicine and palliative care providers or GPs with the approval of a palliative care or pain medicine physician.**

Agree with increased education for health professionals involved in prescribing opioid medications.

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

Agree with increasing awareness of current guidelines for treating chronic pain including the promotion of non-pharmacological strategies and guidance for de-prescribing. We feel that this is an essential component of moving away from reliance on medications and strong opioids in particular as a sole or central strategy in the management of chronic pain. MD NONPHARM ALTERNATIVES, ONLINE

Agree with increased education at both undergraduate and practicing clinician levels.

Agree with defining and implementing 'clinical pathways' for the use of opioids in the acute pain setting. In particular, this should include advice regarding appropriate medications and doses for postoperative or trauma pain relief, limits on the amount of opioid prescribed on discharge, clear expectations on the length of time that strong opioids will be required with instructions for opioid reduction, advice regarding use of non-pharmacological options, arrangements for follow up post discharge and clear communication of the pathway and expectations of opioid use (and reduction) with the local doctor.

Agree with the recommendation to review the regulation of tramadol. Although as noted, the risk is lower than with stronger opioids, there is still a level of risk including overdose fatalities that warrants review of its status.

Additional comments by individual members

Packaging

Blister packs are not child-proof. Many adults carry their medication around with them in wallets and handbags or leave them on bedside tables.

Recommendation: In addition to advice about safe storage, strongly consider making opioid packaging child-resistant to reduce risk in the event of non-compliance with safe storage advice.

Drug disposal

Disposing of unwanted / unused S8 medications can help with preventing diversion, dependence or accidental overdose by household members. The NatRUM (National Return and Disposal of Unwanted Medicines) scheme, run by some community pharmacies can help support this. One avenue to help promote this is by placing a sticker on the S8 box detailing disposal options (as suggested in the NatRUM scheme 2016 Report http://www.returnmed.com.au/wp-content/uploads/2017/08/NatRUM-Project-Final-Report-Griffith-University.pdf).

Increased risk with co-prescription of benzodiazepines

Regulations (through prescribing and education) should also help to address the increased risk of co-prescribing benzodiazepines in people using opioid medications.

Education regarding the time –dependent risk of opioid prescribing

CDC guidelines have shown that there is an increased risk of long term opioid use in people prescribed opioids for more than five days. Therefore efforts should include helping to reduce prescribing beyond 7 days and preferably 3 days in the acute pain setting https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm