Government of **Western Australia**
Department of **Health**

TGA Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

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27 February 2018

Thank you for the opportunity to provide comment on the TGA options for a regulatory response to prescription opioid use and misuse in Australia.

The comments are provided in two sections:

1. Recommendations that address the regulatory options detailed in the paper titled, "Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response" and
2. General recommendations for a nationally co-ordinated response

Section 1: Option Recommendations

Options 1: Consider the pack sizes for Schedule 8 opioids

- Separating opioid product pack sizes based on indication i.e. ACUTE or CHRONIC pain could be beneficial.
- The change in pack sizes would increase awareness amongst medical practitioners and pharmacists about what they are prescribing / dispensing based on the indication. It may also reduce the amount of opioids prescribed as prescribers tend not to write a smaller quantity where the pack size is for a larger or one standard size.
- Smaller pack sizes would require a patient who has been prescribed these high risk medicines to be reviewed at more frequent intervals to ensure effectiveness and appropriateness of treatment.
- In addition, prescriptions for chronic pain should include additional controls for prescribing e.g. mandated use of streamline authorisations to adequately support this change.
- This change will require a change in PBS listing and consideration would have to be given:
    - as to whether this is a cost effective measure and the
    - cost implications for the patient.
- Prescription for each indication should require a management plan to be communicated from the hospital (if appropriate), specialist and/or medical

practitioner, pharmacist and patient as to the duration of the opioids for each indication before being prescribed.

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

- There is agreement for a review to be undertaken to align the indications with current evidence and guidelines, however not convinced this option alone will lead to appropriate prescription.
- It is also proposed that the indication for chronic pain should be linked with therapeutic effectiveness i.e. acceptable level of analgesic response and functional gain, pathophysiological basis for the pain and specific nociceptive, neuropathic or neuroplastic diagnosis.
- However, as most opioids currently are being prescribed for non-cancer type pain unresponsive to non-narcotic analgesia, new indications may be hard to enforce and may be unlikely to impact on prescribing patterns.
- It is further proposed that high dose (>50 - 90MEq/D), high risk opioids (such as fentanyl, methadone and hydromorphone) should only be available in these indications when the patient is under specialist supervision for a condition where pain is not adequately managed / controlled by non-opioid analgesia.

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

- Highest dose products should remain on the market. However, their prescribing should be restricted to prescribers who have received support from an appropriate specialist and the patient is approved to receive opioids at this dose under the relevant state/territory jurisdiction.
- E.g. Products: OxyContin 40mg or higher, MS Contin/Kapanol 50mg or higher, Jurnista 16mg or higher, Fentanyl patches 25mcg/hr or higher.
- Due to high cost of these medicines and other regulatory controls already in place, the risk of prescribers issuing private prescriptions may be minimal. Patient requests for private prescribing of drugs of addiction may also be a red flag to health professionals to seek further information/advice from the state health regulator.
- Some clinicians support restrictions on the use of the highest dose products for NON CANCER pain but not for cancer pain.
- In addition, due to its potency and toxicity and increase in overdose and fatalities, there is growing support that fentanyl should no longer be available for the management of non-cancer pain.

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

- Mandatory funding to be provided by Sponsors for education/training programs for new products to the NPS MedicinesWise on new opioid products is supported.
- NPS MedicinesWise provides an independent and a reputable source of information to health professionals. Reduces impact of sponsor marketing campaigns and conflict of interest.
- Post-market surveillance is an important tool for research, economic analysis and public health policy development to mitigate risk associated with opioid drugs.
- In summary, any move to provide education to clinicians by an independent body such as NPS MedicinesWise is supported.

Option 5: Review of label warnings and revision to the CMI

- Warning labels on drug packaging and information on CMIs is supported. However, not all patients are provided with CMIs and those provided with one may not read it.
- CMI should include revised information about pain and the need to plan for reducing and ceasing opioids prescribed for acute pain.
- Barcoding or QR coding to reduce the risk of diversion is supported.
- Multi-pronged public health interventions have been shown to increase effectiveness of public health programs e.g. tobacco smoking campaign.
- While the CMI changes are supported, a cost-benefit analysis should be undertaken to determine whether the use of warnings on the packaging are beneficial.

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

- Support incentives/expedited TGA review for new products that reduce risk of dependence/addiction/harm and improve patient safety. E.g. new abuse-deterrent technologies.
- While supported in principle, it would be important to ensure that any decision to approve a product (or modification of a product) should have a sound evidence base that includes consideration of unforeseen harms.
- A review of the availability of opioid antidotes and improvement of their affordability is also recommended

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids

- Supported but may be hard to enforce due to limited compliance powers and resources for monitoring programs.
- Different rules between states and jurisdictions exist and may already be sufficient in managing which class of prescriber can prescribe opioids.
- If incorporated in Appendix D this would send a national statement that these medications are to be restricted. However as Appendix D is not mandatory in each jurisdiction, this option will require specific state / territory legislation for the restrictions.
- In WA, there is currently a mechanism that imposes restrictions on the prescribing of S8 medicines and this is **The Schedule 8 Medicines Prescribing Code** (the Code) which is referenced by the WA Medicines and Poison Regulations 2016. In this Code, restrictions for individual high risk S8s as well as pathways to allow general practitioners to prescribe under specified circumstances is provided. For instance, the requirement for authorisation and consultant support is required for all high risk S8 medicines i.e. Methadone and S8 Benzodiazepines and all other S8 medicines and regimens above doses of 90 mg morphine equivalence daily (MEqD).

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

- Education and training for healthcare professionals is supported. Any measures to address the opioid problem will be enhanced if there is collaboration across all relevant agencies, including University medical Schools.
- The creation of standardised and approved education/training modules for opioid prescribing would be helpful for regulators as a compliance tool. Health professionals who fail to adhere to opioid prescribing requirements could be required to complete training modules to have prescribing rights reinstated.
- Training modules could be introduced into clinical workplaces, tertiary education institutions to change culture of prescribing opioids over time.
- To ensure the improvement of public health care outcomes increased Commonwealth funding and accessibility to professional awareness campaigns to the prescribing of opioids and the availability of effective alternatives to opioids etc. would be necessary.

Possible role of Pharmaceutical Benefits Scheme (PBS) prescribing controls

Changes to the PBS listing and approval criteria as discussed would be critical in improving prescribing patterns to opioids.

It is recommended that changes implemented are to be in line with international evidence and national clinical guidelines.

For instance, for fentanyl patches 12mcg/hr (45MEqD) or 100mcg/hr (360MEqD), the PBS criteria are the same: “Chronic severe disabling pain. The condition must be unresponsive to non-opioid analgesics”

As there is a marked difference in potency between the two strengths and with the growing evidence of the toxicity, overdoses and fatalities reported internationally and nationally with Fentanyl, the above PBS criteria should be reviewed for all strengths.

Sections 2: General Recommendations

A co-ordinated multifaceted approach is urgently required to address the widespread misuse and abuse of prescribed opioids in Australia. This overall strategy would require coordination between regulatory bodies, governments, hospitals, professional colleges / organisations, academia, prescribers, pharmacists and consumers in order to reduce potential misuse and harm with the prescription of Schedule 8 (S8) medicines.

In addition to the comments made on each regulatory option above, we suggest that the following strategies be considered:

1. **Proposal for a National committee on Schedule 8 Medicines**
   Such a committee would have the expertise and authority to advise the Federal Minister of Health, States and Territories on policies and procedures to reduce risks in the prescription of S8 drugs, including opioids and benzodiazepines.

2. **Implementation of a Electronic Recording and Reporting of Controlled Drugs (ERCCD) system in each state and territory**
   A nationally coordinated and integrated ERRCD system will make prescribing and dispensing information available in all jurisdictions.

3. **Mandating the use of a national real time prescription monitoring system (RTPM) prior to the issuing of prescriptions and the dispensing of the product.**
   There is strong international evidence that mandatory use of RTPMs by clinicians leads to better health outcomes, including the reduction of doctor shopping and inappropriate prescription.

4. **Increased access to specialist pain and drug treatment facilities**
   Delays of 1-2 years currently exist in WA and in other jurisdictions for patients to access public pain specialists for review of their pain management requirements. Improving access and workforce planning will significantly improve public health outcomes. Although this will require a substantial budget, the cost benefits would be significant.

5. **Improved hospital discharge planning management, and controls on the discharge supply of S8 and S4 medicines**
   General practitioners commonly face problems when their patients are discharged on opioids for pain, with no clear advice from hospital medical specialists as to how and when these medicines are to be tapered and ceased. This often lead to inappropriate long term prescribing of these medicines, leading to dependence and other drug related harms.

6. **Increased education on pain and addiction in medical and other health related undergraduate courses, and in specialist courses provided by colleges.**

7. **A national campaign aimed to address consumer expectations, access to Schedule 8 medicines, non-therapeutic alternatives and their personal responsibilities in relation to their pain medicines and overall health care.**
8. **Investigate the use of electronic technologies such as barcoding and/or S8 medicine tagging.**
   This security approach could assist with monitoring of patient use and diversion of S8 medicines.