

Submission to Therapeutic Goods Administration

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

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Introduction

The Queensland Nurses and Midwives' Union (QNMU) thanks the Therapeutic Goods Administration (TGA) for the opportunity to make a submission to the consultation paper on the *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response*.

Nursing and midwifery is the largest occupational group in Queensland Health and one of the largest across the Queensland government. The QNMU is the principal health union in Queensland covering all categories of workers that make up the nursing workforce including registered nurses (RN), registered midwives (RM), enrolled nurses (EN) and assistants in nursing (AIN) who are employed in the public, private and not-for-profit health sectors including aged care.

Our more than 57,000 members work across a variety of settings from single person operations to large health and non-health institutions, and in a full range of classifications from entry level trainees to senior management. The vast majority of nurses in Queensland are members of the QNMU.

The QNMU supports the TGA in exploring options for a regulatory response to the issues around the use and misuse of opiates in Australia. A balance between the benefits of opioid therapy with the harm of opioids is a key clinical issue (Centers for Disease Control and Prevention, 2016 & Edlund, et al., 2014). Opioids should only be used when the benefits are expected to outweigh the risks (Guy, et al., 2017).

The 'opioid crisis is the latest self inflicted wound in public health' (Makary, Overton & Wang, 2017, p.359). The QNMU acknowledges that regulatory responses are part of a broader process to address the problems of inappropriate or excessive use of opioids. Thus, balanced control measures such as real-time prescription monitoring and enhancing the range of medication pack sizes are such measures that can reduce the 'wounds' and harms associated with opioid use.

While the use of opioids for cancer pain, chronic pain, palliative care and end-of-life care is acknowledged the use of opioids is also highly prevalent in older people and in aged care facilities (Guy, et al., 2017). The use of opioids for this population requires careful attention in achieving optimal pain control and safety (McLachlan, et al., 2011). Safety for all patients across the lifespan is paramount in the use and misuse of opioids.

Option 1: Consider the pack sizes for Schedule 8 opioids

The QNMU supports the option of smaller pack sizes for treatment of patients with acute pain as well as suitable pack sizes for treatment of people with chronic pain. Evidence shows that the duration of opioid use is more important than the daily dose in determining risk for opioid use disorders for people being treated for a new episode of a chronic non-cancer pain (Edlund, et al. 2014). Chances of chronic use begin to increase after the third day supplied. Reducing the pack size would assist in reducing the chances of unintentional chronic use and subsequent dependence (Shah, Hayes & Martin, 2017).

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

The QNMU endorses a review to be carried out of the current indications for the use of strong opioids and aligning the indications to current clinical guidelines and best practice. Regular review of best practice and best evidence will help to ensure that opioid alternatives are incorporated into clinical practice in a timely manner following TGA approval.

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

The QNMU supports the TGA in reviewing the place of higher dose S8 opioid products. The treatment of cancer pain, chronic pain and palliative care may require higher doses of opioids for effective pain management and should be considered. Evidence-based models of care must direct best practice for these situations as this will help to ensure that perverse consequences do not occur for specific patient groups requiring high dose opioid drugs (e.g. unnecessary barriers to prescribing and obtaining high dose opioids), in the context of a more general review of S8 opioid availability and use.

Lessons regarding availability, should be drawn from the medicinal cannabis down-scheduling process. Difficulties owing to differing state bureaucracies concerning the process of prescribing, access and supply of medicinal cannabis, should be avoided for opioid use in Australia (Martin, 2014).

Option 4: Strengthening Risk Management Plans for opioid products

Reviewing the risk management plans for opioid products is supported by the QNMU. To this end, the nationalisation and standardisation of legislation that incorporates state and territory legislation pertaining to scheduled drugs would strengthen risk management.

In a report by the Office of the Health Ombudsman (2016) (Qld) (OHO) the framework for regulating S8 medicines in Queensland was examined. Deficiencies were identified in the coordinated inter-government (state) department approach particularly:

... the coordination of roles and responsibilities between relevant agencies involved in regulating and responding to emerging prescribing and dispensing concerns with schedule 8 medicines. This lack of coordination underlies many of the risks associated with agency responses to prescribing and dispensing issues with schedule 8 medicines in Queensland (Office of Health Ombudsman, 2016, p.6-7).

Whilst the OHO report looked at 'undoing the knots constraining medicine regulation in Queensland' it's likely these issues are also experienced by other states. A clear national, standardised approach may be timely to strengthen risk management plans for opioids.

The QNMU strongly recommends the establishment of national real-time prescription monitoring system to reduce the risks associated with opioid over-prescribing. Such systems have been established in some states, however we believe there should be a national approach to real-time prescription monitoring, given the lengths that dependent persons go to in order to obtain the product.

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

The revision of Consumer Medicines Information (CMI) and label warnings is supported by QNMU. The risks and appropriate use of opioids should be consistent across the box labels, production information (PI) and CMI and include the risk of dependence and overdose.

With the growing interest by health consumers for health information and engagement in health care decision-making, it is essential to make health information available to patients and easy to understand (Haga, Mills & Moaddeb, 2014). This health and drug information should be conveyed using a multi-prong approach with health practitioners being the primary source for information and labels, PI and CMI supporting this discussion.

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

The provision for a priority review of therapeutic alternatives to opioids and the treatment of pain is commended by the QNMU. As is the development and review of opioid antidotes as these can be used to mitigate the risks associated with overdose and misuse of opioids.

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

Any changes to the use of appendices in the Poisons Standard should involve consultation with affected stakeholders.

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

The QNMU supports increasing health practitioner awareness of the alternatives to opioids in the management of pain. For nurse practitioners and midwives, continuing professional development (CPD) requires twenty hours of CPD and for endorsement nurse practitioners and midwives are required to complete ten additional hours relating to prescribing and administration of medicines (Nursing and Midwifery Board of Australia, 2018). Pain management and the use of opioids and alternatives to opioids could be incorporated into this CPD.

Conclusion

A regulatory response to opioid use and misuse in Australia is supported by the QNMU. These actions proposed by the TGA are a necessary part of the larger picture of dealing with the opioid crisis.

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