AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D18-4502

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John

Dear Professor Skerritt

Prescription strong (Schedule 8) opioid use and misuse in Australia

I am writing in response to the Therapeutic Goods Administration's (TGA) consultation on 'Prescription strong (Schedule 8) opioid use and misuse in Australia - options for a regulatory response' opened in January 2018. The Australian Commission on Safety and Quality in Health Care (the Commission) commends the TGA for initiating the consultation and the regulatory review to promote safe and appropriate use of strong opioids.

The Commission's work plan has a strong focus on high risk medicines. As part of this, the Commission is consulting on the development of a national plan in response to the third World Health Organization Global Patient Safety Challenge – Medication Without Harm, launched in 2017. The Commission will consult with the TGA in the development of the national plan. More information on the Challenge is available at:

www.who.int/patientsafety/medication-safety/en/

The Commission notes that strong opioids are effective in relieving moderate to severe pain, particularly acute and cancer pain[1], and the lack of evidence for using opioid therapy in chronic non-cancer pain. Notwithstanding, the prescribing of opioids for chronic non-cancer pain is increasing as are the adverse effects associated with long-term use.[2,3,]

As context:

- The Commission published the first edition of the Australian Atlas of Healthcare Variation in 2015. Using 2013-14 data the Atlas showed that the number of PBS-listed opioid medicines dispensed across 325 local areas (SA3s) ranged from 10,945 to 110,172 per 100,000 people. This represents a tenfold difference between the area with the highest and the area with the lowest rate. The Atlas series is available on the Commission's website at:

  www.safetyandquality.gov.au/atlas/

  Dispensing rates for opioids were higher in areas of low socioeconomic populations and higher in rural and regional areas. Opioid dispensing rates will be revisited as part of the third Atlas, and the findings shared with the TGA to inform this regulatory review.

- Australia's *National Medicines Policy* promotes equitable access to pharmacological intervention as one of several management options for treating illness and maintaining health. It promotes an evidence-based approach to choosing suitable medicines if a medicine is considered necessary, and the quality and safe use of that medicine.

- The *National Pain Strategy* takes an integrated approach to improving acute, chronic and cancer-related pain. The pain strategy outlines the contribution of an

interdisciplinary, targeted approach to pain management alongside medication and is available at:
www.painaustralia.org.au/improving-policy/national-pain-strategy

- The pain strategy emphasises the need for access to chronic pain prevention and early intervention programs. An example of an integrative approach to pain management is the Commission's Clinical Care Standard (CCS) for Osteoarthritis of the Knee (OAK). The standard highlights the limited role of opioids in osteoarthritis pain management, and is available at:
www.safetyandquality.gov.au/our-work/clinical-care-standards/osteoarthritis-clinical-care-standard/

The Commission strongly supports a number of the options proposed by the TGA. Appendix 1 presents the Commission's high-level response to the options. In particular, the Commission recommends prioritising opioid prescribing guidelines for acute and primary care, availability of smaller pack sizes for treatment of acute pain at discharge after surgery, and different strategies for acute and chronic pain management noting the need to categorise patients who are opioid naïve and those with history of chronic use.

The prescribing and supply of strong opioids involves a number of steps. Regulatory changes may impact behavioural responses of clinicians and patients. A collaborative approach to influencing behaviour in the community should be considered alongside regulatory changes.

The Commission would be happy to support further consultation with the TGA and other stakeholders. For any further information please contact:

[redacted]

Yours sincerely

[redacted]

Adjunct Professor Debora Picone AM
Chief Executive Officer

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1. Macintyre P, Schug S, Scott D, Visser E, Walker S. Acute Pain Management: Scientific Evidence (3rd edition). APM: SE Working Group of the Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine. Melbourne: ANZCA & FPM, 2010
2. Hunter Integrated Pain Service. Reconsidering Opioid Therapy. A Hunter New England Perspective. Newcastle: HIPS, 2014
3. Blanch B, Pearson SA, Haber PS. An overview of the patterns of prescription opioid use, costs and related harms in Australia. BJCP. 2014;78(5):1159–66

Appendix 1: Options for a regulatory response

This response from the Australian Commission on Safety and Quality in Health Care (the Commission) to the options for improving the safe and effective use of strong prescription opioids presented by the Therapeutic Goods Administration (TGA) addresses options 1,2,4,5,7 and 8.

Option 1: Consider the pack sizes for Schedule 8 opioids
Supported. The availability of smaller pack sizes reimbursed under the PBAC will drive the prescription of smaller, more appropriate quantities of opioids for management of acute pain, particularly on discharge from hospital after surgery. Larger pack sizes should still be available to meet the needs of those patients for whom extended use of opioids is indicated.

Option 2: Consider a review of the indications for strong opioids
Supported. Indications should be considered in line with the pack sizes. This aligns with the Commission's response to option 8 (below), as indication can reflect use after other options have been considered.

Option 3: Consider whether the highest dose products should remain on the market or be restricted to specialist/authority prescribing
The Commission would be happy to support further discussion on this option. In particular, access to specialist pain and palliative care services in regional and rural areas can present difficulties when restricting prescribing of specific medicines.

Option 4: Strengthening risk management plans for opioid products
Supported.

Option 5: Review of label warnings and revision to Consumer Medicines Information (CMI)
Supported. Mandatory labelling for high risk medicines will promote safe use and is an additional safety factor which can be reiterated in the CMI. Human factors analyses and consumer testing can be used to identify the most appropriate wording.

Option 6 Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes
The Commission is happy to be involved in further discussions regarding this option.

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids
Supported. Considered in line with Options 1, 2 and 8

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain
Supported. Prescribing guidelines for strong opioids and more broadly prescribing guidelines within pain management for as a collaborative approach are essential to inform existing and future regulatory policies.

In addition, the increased regulation of tramadol from prescription only to Schedule 3 (Controlled Drug Non register) in the UK is referred to on page 21 of the consultation paper. Since this change in 2014, the number of recorded deaths from tramadol has reduced. The Commission recommends the review of tramadol regulation in light of these results.