

2 March 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

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

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback to the Therapeutic Goods Administration's consultation on prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response. We strongly support the purpose of the proposed reforms to address opioid misuse.

The RANZCP is the principal organisation representing the medical speciality of psychiatry in Australia and New Zealand and is responsible for training, educating and representing psychiatrists on policy issues. The RANZCP represents more than 6000 members, including more than 4000 qualified psychiatrists, and is guided on policy matters by a range of expert committees, including the Faculty of Addiction Psychiatry. The RANZCP is concerned about the increasing use of opioids which are associated with significant morbidities and mortalities across both physical and mental health dimensions. As the peak body representing psychiatrists in Australia, we are particularly aware of the biopsychosocial determinants of the pain experience and how this can affect an individual's use of opioids, including with regard to the development of chronic pain and/or opioid dependence.

The RANZCP supports each of the proposed regulatory options including:

- requiring sponsors to register and make available for supply suitable pack sizes, including smaller sizes for the treatment of patients with acute pain, including clear delineation of indications for long- and short-term use
- review of indications for Schedule 8 opioids and alignment with current clinical guidelines
- safety review of the risk–benefit ratio for higher dose Schedule 8 opioid products, with a view to specifying authority prescribing for the Pharmaceutical Benefits Scheme



- review of current risk management plans to ensure they reflect best practice in prescription and risk management practices – in particular, we note our support for the inclusion of biopsychosocial determinants of pain in any educational programs to be developed
- inclusion of warning labels of opioid product packaging identifying the risk of dependence and overdose, and efforts to obtain suitable changes to Consumer Medicines Information leaflets
- priority/expedited review for alternatives to opioids for pain reliefs, smaller pack sizes and abuse-deterrent formulations and products
- additional controls in the Poisons Standards concerning prescribing for particular populations or classes of medical practitioners, or additional safety directions or label warning statements, as appropriate for individual products – we would also note our support for any legislative reform that may be required to facilitate this
- work to increase awareness of appropriate pain management guidelines among health practitioners to promote appropriate use of non-pharmacological interventions
- further restrictions that may be facilitated via the Pharmaceutical Benefits Scheme.

We would also advocate for measures to reduce the current disparity in ease of access to medication-assisted treatment for opioid dependence when compared to other opioids. In particular, we would suggest that the Pharmaceutical Benefits Scheme cover the dispensing costs of methadone, buprenorphine and buprenorphine/naloxone which are significantly higher than for other opioids available on prescription, despite their usefulness in helping Australians to recover from opioid dependence.

The RANZCP would also note its support for a further review of Schedule 4 opioids which, though posing a lower risk than their Schedule 8 counterparts, still require an appropriate regulatory response to address misuse.

If you would like to discuss any of the issues raised in the submission, please contact

[Redacted contact information]

Yours sincerely

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