

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

1 March 2018

Dear Sir or Madam,

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

The Australian and New Zealand Society of Palliative Medicine (ANZSPM) appreciates the opportunity to provide comments on this consultation.

ANZSPM notes the purpose and scope of the consultation paper and supports the overall aim to improve the quality use of opioids and to ensure the alignment of clinical practice with the evidence base. We support measures to prevent prescription of opioids for indications where there is evidence for lack of benefit. However, it is also important that evidence for the efficacy of opioids in cancer pain is also taken up into practice, as unrecognised and under-treated cancer pain remains a clinical challenge. Barriers to appropriate use of opioids should not be the result of regulatory change.

We provide below feedback on the options listed, in the specific context of people with chronic cancer pain and pain in the context of non-malignant life limiting illness.

About ANZSPM

ANZSPM is a specialty medical society that facilitates professional development for its members and promotes the practice of Palliative Medicine in order to improve the quality of care for people with life threatening illness.

Our members are medical practitioners who provide care for people with a life-threatening illness and include palliative medicine specialists, palliative medicine training registrars and other doctors such as general practitioners, oncologists, haematologists, intensivists, psychiatrists and geriatricians. ANZSPM currently has approximately 480 members, with more than 350 of our members in Australia.

ANZSPM comment on options for a regulatory response

Option 1:

ANZSPM supports the consideration of a broader range of pack sizes. We however highlight that there are patients who have non-malignant life limiting conditions who require opioid analgesia and

hence limiting the large pack sizes to people with chronic pain due to malignancy will impact on the care of such patients.

Option 2:

ANZSPM supports the review of indications S8 opioids and alignment with clinical practice guidelines. We point you to the Australian Cancer Pain Management in Adults available at: https://wiki.cancer.org.au/australia/Guidelines:Cancer_pain_management

We also note there are clinical scenarios where there is currently absence of evidence or emerging evidence and that the profile of cancer pain is heterogeneous. Increasingly a large number of people with active cancer have an expected longer-term survival, cancer patients may have pre-existing and/or concurrent non-malignant pain; or have multi-morbidity contributing to mixed cancer and non-cancer pain. The use of opioids for palliation of chronic breathlessness is also well supported by clinical trial evidence and recommended in several international guidelines^{1 2} and needs to be considered. ANZSPM would welcome discussions to consider how the indication listings would accommodate clinical needs for palliative care patients who fall in these categories. ANZSPM also supports further research in these conditions.

Options 3 and 7:

ANZSPM supports the principle that opioid prescribing, especially with higher doses should be by clinicians with the necessary clinical expertise and training, and specialist input is often warranted.

However, we highlight that both options 3 and 7 could lead to significant disparities in access, with a shortage of both palliative medicine and pain specialists, particularly shortages in regional and rural areas. Flexibility is also needed to ensure palliative care patients who no longer are able to attend ambulatory services as their condition deteriorates can continue on their medications under the supervision of their primary care physicians, if community specialist access is limited or clinical re-assessment at specialist level is not required.

Option 4:

ANZSPM supports the consideration of improved risk management plans and wider education. Importantly this needs to capture a broad range of junior medical staff, trainees, general practitioners, and medical and surgical specialists, and be regularly updated to ensure currency of practice.

In the field of palliative care, it is also important to consider education of nurse practitioners, and also senior clinical nurses who will be providing clinical advice about opioids to medical teams. In many cases it is also appropriate to consider allocation of a single prescriber, or a small group of core prescribers (one GP and one specialist for example with clear communication), except in situations of clinical urgency.

Education should include management of cancer pain in which there is established efficacy of opioids.

¹ Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. Available from: <http://goldcopd.org/>

² Mahler DA, Selecky PA, Harrod CG, et al. American College of Chest Physicians consensus statement on the management of dyspnea in patients with advanced lung or heart disease. *Chest* 2010;137:674–91.

Option 5:

ANZSPM supports accurate consumer information, however as noted there is a complexity in the appropriate management of chronic pain, including in the palliative setting. Many patients with cancer pain have misconceptions and concerns about opioids, and consumer information should not indirectly lead to barriers to the adequate management of pain in the palliative setting if an opioid is indicated. Consumer information should also be available in other languages other than English.

Option 6:

ANZSPM supports the consideration of approaches to respond to an application for registration for products for pain relief, noting that this would still review full safety, efficacy and quality data. However, more immediately, a Government approach to support and encourage access to new agents in the clinical trial context (both investigator-led and pharmaceutical company sponsored) would also improve capacity for Australian patients to have access to a broader range of analgesic options.

Option 8:

ANZSPM acknowledges that guidelines are often not translated into practice. ANZSPM supports education and training as a priority area. In particular, clinicians need to understand appropriate methods for the screening and assessment of pain, and have a comprehensive understanding of pharmacological and nonpharmacological approaches to pain management tailored to a variety of clinical conditions. Competencies are also required in assessing and managing risks of opioid misuse whilst supporting adequate analgesia in clinical scenarios where the evidence supports opioids are clinically indicated. ANZSPM would welcome the opportunity to contribute expertise to mandatory education modules.

We would appreciate the opportunity to be involved in future discussions to ensure further considerations of regulatory approaches are informed by expert palliative medicine specialists and consider the needs of palliative care patients.

Please contact Chief Executive Officer Simone Carton if further information relating to our response is needed.

Yours faithfully,

Prof Meera Agar
President

Simone Carton
Chief Executive Officer