

# Arthritis Australia submission to the TGA consultation on Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

## Introduction

Arthritis Australia welcomes the opportunity to provide a submission to the TGA's consultation on options for a regulatory response to prescription strong (Schedule 8) opioid use and misuse in Australia.

While this consultation focuses on regulatory approaches to managing harms associated with opioid use, we would like to emphasise that the opioid problem is primarily a symptom of a broader problem, relating to significant unmet need for safer and more effective pain management approaches, that requires a comprehensive strategy to resolve.

There is a pressing need to improve pain management in Australia including:

- More effective treatment and management of the underlying conditions associated with chronic pain, as well as chronic pain itself.
- Increased utilisation of non-pharmacological approaches to pain management, including better access to affordable, appropriate multidisciplinary care for management of chronic pain and of the underlying conditions associated with chronic pain.
- Increased education and training in effective pain management strategies, including the limited role of opioids, for health care practitioners.
- Increased research into effective pain management, including safer and more effective pharmacological management options, better understanding of pain pathways, methods for preventing the transition from acute to chronic pain and better management and cures for conditions associated with chronic pain.

In this context we note and support the key points raised at the Opioids Roundtable held in Canberra in May 2015 and reported in the consultation paper, which discussed the broader context and issues associated with opioid use and misuse.

### Background

Musculoskeletal conditions are the leading cause of chronic non-cancer pain and are the leading health problems for which opioids are prescribed in primary care, accounting for nearly 60% of opioid scripts in Australia in 2011, most commonly for back pain (1 in 4 opioid scripts) and osteoarthritis (OA) (1 in 10 scripts).<sup>1</sup>

However, there is limited evidence to support longer-term opioid use in OA or in chronic back pain, with small to moderate benefits in pain and function outweighed by the risk of adverse events.<sup>2 3</sup> Weak opioids may be effective in short-term management of pain associated with rheumatoid arthritis, but again there are concerns that adverse events may outweigh these benefits and there is limited evidence relating to the impacts of longer term use.<sup>4</sup>

Effective management of the underlying condition is an important strategy in managing the pain and other symptoms associated with different forms of arthritis. For osteoarthritis, physical activity, weight loss and self-management strategies are effective in reducing improving symptoms such as pain and reduced function, yet uptake of these strategies in Australia is poor. For rheumatoid arthritis, early diagnosis and treatment with disease-modifying anti-rheumatic drugs can increase the prospect of achieving disease remission and reduce the severity of the condition over the longer term, while improved psychosocial support can also help to reduce pain and fatigue. Yet delays in diagnosis and initiation of treatment are common and access to psychosocial support through the health system is limited. Improving care for these conditions can help to reduce reliance on opioids for pain management in people with arthritis.

Nonetheless, many people with arthritis report that opioid medications can help to manage their pain during periods when they are experiencing an aggravation of their condition. This is supported by evidence suggesting that some people with chronic non-cancer pain experience clinically significant pain relief with opioids, with only minor adverse events.<sup>5</sup> This suggests that while long-term opioid use for chronic non-cancer pain should be minimised, when considered necessary and appropriate, use needs to be carefully and judiciously monitored.

#### **Proposed** option

#### Option 1: Consider the pack sizes for Schedule 8 opioids.

We support this option, with the proviso that larger pack sizes be made available for chronic non-cancer pain when opioid prescribing is considered appropriate.

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

We support this option to review indications for the S8 opioids and align them to current clinical guidelines.

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

We note that higher dose opioids may be important in certain clinical contexts such as palliative care. Specialist-only/authority prescribing is also likely to be onerous for prescribing doctors.

#### Option 4: Strengthening Risk Management Plans for opioid products

We support this option. In particular we strongly support the development and delivery of an educational program for health care providers, as suggested, which addresses the role (or otherwise) of opioids in the broader context of pain management.

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

We support this option.

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

We support this option, but note that due to the lack of new agents on the immediate horizon, it is unlikely to be of any benefit in the short to medium term.

Option 7: Changes to use of appendices in the Poisons standard to provide additional regulatory controls for strong opioids.

We suggest that additional consultation would be required for this option, depending on the nature of the additional regulatory controls proposed. Approaches which require education of health professionals in appropriate pain management strategies would be supported.

#### Option 8 Increase health care professional awareness of alternatives to opioids in the management of chronic pain.

We strongly support this option. In particular, there is a pressing need to educate and or/raise health professional awareness of non-pharmacological strategies for managing chronic pain, in line with appropriate pain management guidelines. However, to be effective, this approach must be complemented by improved patient access to affordable, appropriate multidisciplinary care for management of chronic pain and of the underlying conditions associated with chronic pain.

PBS prescribing controls requiring specialist review prior to prescription, telephone authority or restriction of prescribing to certain prescribers, such as rheumatologists for arthritis pain, are likely to be onerous and would increase demand for limited specialist services that are already stretched. In addition, people for whom opioid therapy is appropriate will face additional costs and inconvenience to access their therapy. This is likely to be a particular problem for people in rural and regional areas who commonly have limited access to specialist prescribers.

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<sup>&</sup>lt;sup>1</sup> Harrison CM, Charles J, Henderson J, et al. Opioid prescribing in Australian general practice. Med J Aust 2012;196:380–1.

<sup>&</sup>lt;sup>2</sup> Chaparro LE, Furlan AD, Deshpande A, et al. Opioids compared to placebo or other treatments for chronic lowback pain. Cochrane Database Syst Rev 2013;8:CD004959.

<sup>&</sup>lt;sup>3</sup> Da Costa BR, Nuesch E, et al. Oral or transdermal opioids for osteoarthritis of the knee or hip. Cochrane Database Syst Rev 2014 Issue 9. Art. No.: CD003115. DOI: 10.1002/14651858.CD003115.pub4

<sup>&</sup>lt;sup>4</sup> Whittle SL, Richards BL, et al. Opioid therapy for treating rheumatoid arthritis pain. Cochrane Database Syst Rev 2011 Nov 9;(11):CD003113. doi: 10.1002/14651858.CD003113.pub3

<sup>&</sup>lt;sup>5</sup> Noble M, Treadwell JR, Tregear SJ, et al. Long-term opioid management for chronic noncancer pain. Cochrane Database Syst Rev 2010:CD006605.