Australian Rheumatology Association

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2 March 2018

[redacted]
Technical and Safety Improvement Section Pharmacovigilance and Special Access Branch
Medicines Regulation Division
Department of Health
PO Box 100
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Via email: PSABCommunications@health.gov.au

Dear [redacted]

Thank you for giving the Australian Rheumatology Association the opportunity to comment on: **Prescription Strong (schedule 8) Opioid Use and Misuse in Australia – Options for Regulatory Response.**

The Australian Rheumatology Association (ARA) is a specialist society within The Royal Australasian College of Physicians. We are experts in the diagnosis and management of people with arthritis, rheumatic and other musculoskeletal conditions.

Like you we are concerned about the increases in opioid prescriptions for osteoarthritis, and we are similarly concerned about use of opioids to treat both acute and chronic low back pain, inflammatory arthritis and other musculoskeletal conditions. We agree that for most of these conditions, not only is there no strong evidence-based rationale for their use, the benefit to risk profile is also unfavourable.

Option 1: We agree with both of the changes proposed (to make the pack sizes smaller for treatment of people with acute pain and to make allowances for people with pain due to cancer).

Option 2: We fully support the conduct of a review of the indications for strong (S8) opioids including a review of existing Cochrane and other high quality systematic reviews, as well as available clinical practice guidelines. There are several existing reviews within Cochrane Musculoskeletal on this topic although some may need updating to include more recent trials (if any have been performed).

A 2011 Cochrane review of opioid therapy for treating non-inflammatory pain in rheumatoid arthritis concluded that there was limited evidence that weak opioids may be effective analgesics for some people with rheumatoid arthritis but adverse effects were common and may offset the benefits. There was insufficient evidence to draw conclusions about the role of weak opioids for longer than six weeks, or the role of strong opioids. (Whittle SL, Richards BL, Husni E, Buchbinder R. Opioid therapy for treating rheumatoid arthritis pain. *Cochrane Database of Systematic Reviews* 2011, Issue 11. Art. No.: CD003113.) Similarly our conclusions about opioids for osteoarthritis based upon another Cochrane review were that they also have a limited role (Howes F, Buchbinder R, Winzenberg T. Opioids for osteoarthritis. Weighing benefits and risks: A Cochrane *Musculoskeletal Group review. J Fam Practice* 2011;60(4):206-12).

Option 3: We think it would be reasonable to make higher dose S8 opioid products available only when prescribed by specialists or authority prescription. Patients with non-cancer pain who appear to require ongoing higher dose opioids should be assessed by a specialist in the condition being treated (e.g. a rheumatologist for musculoskeletal conditions or when timely assessment is not possible then in consultation with a specialist). In particular, this would ensure that people with chronic pain do not

Option 4: We agree with Option 4 that there be a review of current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.

Option 5: We agree with Option 5 that there be a review of label warnings and revision to the Consumer Medicines Information. In particular we wonder why there are no black box warning on the packets of S8 or for that matter S4 medications currently in view of the potential for significant harms with these medications. It would also be important to ensure the language is easily understandable by all patients irrespective of their level of literacy and health literacy and this should also be available in the first language of the patient receiving the medication.

Option 6: We agree with Option 6 provided that expedited TGA review still means that a high quality evidence-based review of the evidence for both the efficacy and safety of these new medications is performed.

Option 7: We agree that consideration should be given to include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, and specific dispensing labels. In particular, we think that a review of the diagnosis and appropriateness of management should be performed by a specialist in the field after a period of time, most probably no longer than three months from presentation/prescription of opioids. This would ensure that the correct diagnosis has been made. This is of particular importance for inflammatory arthritis such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile arthritis where highly effective treatments that both controls symptoms and prevent disease progression and joint damage are available. In these situations early diagnosis and treatment is optimal.

Option 8: We also strongly agree with Option 8. It is imperative that there is increased health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain.

The Australia Rheumatology Association would be happy to have further discussions with the TGA on this important area of management of our patients.

Yours sincerely

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President