



2 March 2018

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

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

Medicines Australia (MA) welcomes the opportunity to respond to the TGA's Consultation paper on Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response.

The key focus for MA and its member companies is the health and wellbeing of consumers. MA believes that it is therefore vital that in addition to sponsors/manufacturers' views, consumers' opinions need to be closely considered in compiling a regulatory response to this complex issue.

MA recognises the need for fit for purpose regulations to support the appropriate use of S8 opioids in Australia, balancing the risks associated with the use and misuse of opioids whilst also acknowledging the critical role that opioids play in managing severe acute pain following trauma and major surgery, as well as pain caused by cancer and various other conditions.

Whilst there are already processes in place to support the appropriate use of S8 medications, any increase in the restrictions around the use of S8 medications needs to strongly consider the needs of patients suffering the burden of pain and their access to services, support and timely pharmacotherapy. Moreover, we believe that changes made as a result of this consultation process must be based on the individual risk profile of S8 analgesics, and not applied to the entire class in a non-specific fashion, given developing bodies of research and the needs of Australians living with pain.

MA notes that a multimodal approach to pain management, including appropriate pharmacotherapy, is proven and effective. It is also important to consider those suffering chronic pain compete for a finite number of pain services in Australia with long wait times. These services may be further limited for Australians living in rural and regional Australia where local access is rare. As a result, the burden of pain management in Australia falls to general practitioners; in fact, one in every five GP consultations involves a patient with chronic pain¹, highlighting the ongoing importance of educating health professionals in pain management. Therefore, we support increased education for GPs, so that they can understand how to best support their pain patients and know which services they can use to support patients getting back to being able to function in life.

In such a complex area, it is important that consultation continues to take place on any proposed further options so that there can be an appropriate balance for patients needing to access services and pharmacotherapy and options that mitigate misuse.

We expect that those MA member companies whose portfolio includes opioids, will respond to this consultation separately as well.

We would appreciate being kept informed of further steps in this process and correspondence on this matter can be addressed either to myself (tel. 02 6122 8525, email: edesomer@medaus.com.au) or my Regulatory Policy Manager, Ms Larissa Karpish (tel. 02 6122 8519, email: lkarpish@medaus.com.au).

Yours sincerely

A handwritten signature in black ink, appearing to read 'E. de Somer', written in a cursive style.

Elizabeth de Somer
Director, Policy & Research