

02 March 2018

Therapeutic Goods Administration PO Box 100 Woden ACT 2606 Australia

Dear Sir or Madam,

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

welcomes the opportunity to review the consultation document on Prescription strong (Schedule 8) opioid use and misuse in Australia.

Option 1: Consider the pack sizes for Schedule 8 opioids

Require sponsors to register and make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28-day) for treatment of people with chronic pain due to malignancy.

does not support Option 1. proposes that educating health practitioners and patient groups as per Option 8 would improve the appropriate use of S4 and S8 opioids. Effective implementation would provide the necessary risk minimisation to negate the requirement for smaller pack sizes.

Mandating the registration and supply of smaller pack sizes (such as maximum three-day packs) may lead to a lack of commercial viability of these products. Many sponsors may be forced to cancel registrations for the current pack sizes (28 or 30 packs) due to difficulties supplying the smaller packs. Cancellations of current registrations will result in a sole supply market for certain molecules, which may increase the risk of Medicines Shortages of critical pain management products.

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

The TGA will review indications for the S8 opioids and align them to current clinical guidelines for appropriate prescription of these products.

supports Option 2.

Option 4: Strengthening Risk Management Plans for opioid products

Review current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.

does not support Option 4. The current effective EU RMP maintains the benefit risk profile with safety concerns managed effectively through routine pharmacovigilance and routine risk minimization (the SmPC).

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain

Existing clinical guidelines for the management of acute and chronic pain provide advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain. While these are available there may be limited health practitioner awareness and uptake.

supports Option 8. Implementation of a widespread education program through a provider, such as NPS MedicinesWise with support from clinical colleges and societies, can increase health practitioner awareness on existing clinical guidelines in order to change prescribing patterns and increase Quality Use of Medicines.

Sincerely,

