

[REDACTED]

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**

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

[REDACTED]

**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.*

[REDACTED] does not support Option 1. [REDACTED] 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.

