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Thank you for the opportunity to comment on your Consultation Paper – **Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response.**

The Paper is impressive and comprehensive, and I think covers the potential options open to the TGA very well. Another important step will be through prescription monitoring, using the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system.

Out of interest, after your presentation to the ACM, I wrote a snippet for our Hospital Drugs and Therapeutics bulletin as part of an education strategy to try and help rationalise opiate prescribing in our hospital.

Kind regards,

[REDACTED]

Here is my (brief) response to the possible options:

Options for the regulation of strong (S8) prescription opioid medicines

Option 1 – Pack size

Supported. Require 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.

Option 2 – Review of indications for strong (S8) opioids

Supported. Review indications for the S8 opioids and align them to current clinical guidelines for appropriate use.

Option 3 – Restrict highest dose products to specialist/authority prescribing

Supported. Review the place of the higher dose S8 opioid products in the management of chronic cancer and non-cancer pain. Should predominantly be restricted to cancer pain and to palliative care, oncology or specialist pain clinics. PBS restrictions could help achieve this.

Option 4 – Strengthening of RMPs for opioids

Supported. Current risk management plans for opioids should be reviewed to determine whether they reflect best practice in opioid prescribing and management of risks.

Option 5 – Review and revision of CMIs

Supported. Warnings should be placed on the packaging, identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of chronic non-cancer pain.

Option 6 – Expedited review of promising new products

This has some merit

Option 7 – Potential changes to use of appendices in the Poisons Standard

Supported. More control required of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels.

Option 8 – Increase awareness of alternatives to opioids in chronic pain

Supported. Education is most important. Agree that the TGA should work with the NPS MedicinesWise and clinical colleges to increase awareness of healthcare practitioners and the uptake of appropriate pain management guidelines in their practices.

Option 9 – PBS restrictions to be expanded

An important strategy will be restriction of PBS subsidy for certain opioids/indications/quantities. The TGA should work closely with the PBS to achieve this.

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