

CONSULTATION: PRESCRIPTION STRONG (SCHEDULE 8) OPIOID USE AND MISUSE IN AUSTRALIA – OPTIONS FOR A REGULATORY RESPONSE

Thank you for the opportunity to comment on the options for a regulatory response to prescription strong opioid analgesic use and misuse in Australia.

1. CONSIDER THE PACK SIZES FOR SCHEDULE 8 OPIOID ANALGESICS

We strongly support the introduction of **smaller pack sizes for both long-acting and immediate-release S8 opioids and tramadol**.

Smaller pack sizes are likely to reduce stockpiling, risk of harms, and diversion or sharing with friends and family,¹ and would be particularly useful in light of the increasing trend in strong opioid prescribing (particularly oxycodone) on **hospital discharge**.² The majority of patients prescribed opioids on discharge receive more than they need,^{1,3} and about 10% of opioid-naïve patients receiving opioid analgesics on discharge become long-term users.^{4,5} The emergency department is also a known target for individuals seeking opioids for extra-medical use.⁶

Very small pack sizes (e.g. 3 days' supply) should be available for **long-acting as well as immediate-release opioids** as reports suggest that Australian Pain Services and hospitals are now prescribing modified-release oxycodone/naloxone formulations in preference to other oxycodone formulations, even for acute pain.^{2,7,8} Many Australian GPs also preferentially prescribe modified-release formulations over immediate-release forms.⁹

Small pack sizes are likely to be widely prescribed given the concerns about opioid misuse in the medical profession.

2. CONSIDER A REVIEW OF THE INDICATIONS FOR STRONG OPIOID ANALGESICS

There is a need to review the indications for strong opioid analgesics to align with the evidence on efficacy, safety and **quality of life/global functioning**, with an aim to narrowing the current indications for use. These changes could be implemented at the regulatory level or through the PBS in consultation with the PBAC. Specifically,

- Use should be restricted to patients who are ***intolerant to or have failed an adequate treatment trial of non-opioid analgesics***.
- Certain conditions, such as osteoarthritis, headache, migraine¹⁰ or chronic low back pain¹¹ may warrant exclusion from the list of approved indications due to poor evidence for efficacy.
- Short-acting opioid analgesics should be indicated only for **acute or breakthrough** pain.

3. CONSIDER WHETHER THE HIGHEST DOSE PRODUCTS SHOULD REMAIN ON THE MARKET, OR BE RESTRICTED TO SPECIALIST/ AUTHORITY PRESCRIBING

We support restricting the availability of high-dose opioid analgesics, whether by restricting availability/prescribing or removing the products from the market.

We suggest:

- At the very least, remove or restrict prescribing of 100ug/h fentanyl patches. Preferentially, restrict prescribing of **all fentanyl transdermal drug delivery systems** and **hydromorphone formulations**,¹² regardless of strength, to appropriate specialists (oncologists, palliative care, pain specialists) and authorised/trained GPs.
- **Remove 80 mg modified-release oxycodone tablets** from the market, but **retain 80 mg/40mg oxycodone/naloxone tablets under restricted prescribing conditions**. Like modified-release (reformulated) oxycodone tablets, oxycodone/naloxone deters misuse by non-oral routes, and may also deter oral misuse through precipitating withdrawal in heavy opioid users or through systemic naloxone absorption at higher doses.^{13 14}
- **Remove generic modified-release oxycodone formulations** that lack abuse-deterrent properties from the market.

4. STRENGTHENING RISK MANAGEMENT PLANS FOR OPIOID PRODUCTS

Educational programs:

- We particularly advocate for educational programs targeted at medical practitioners (especially junior doctors) regarding **appropriate opioid analgesic prescribing on hospital discharge**⁴⁵ and ensuring **adequate transfer of patient care to the community**.
 - Educational programs that have been successful in reducing inappropriate inpatient and discharge prescribing include St Vincent's Hospital Sydney's 'Opioid stewardship...a new approach to safe opioid discharge prescribing' and the New Zealand Capital and Coast District Health Board (CCDHB) Pharmacy Integrated Care Collaborative (ICC) Opioid Safety initiative.^{2 15}
- We also support pharmacy-led initiatives, such as the opioid stewardship program being implemented across the South East Sydney Local Health district (SESLHD).¹⁶ Pharmacy-led initiatives have previously shown success in anti-microbial stewardship.¹⁷
- Educational programs should also address the risks of **co-prescribing opioid analgesics with other CNS depressants**, the importance of checking the patient's current use of other medicines (over-the-counter and prescription) and alcohol, and the additional risks associated with mental health problems.
- Educational material should be prepared, funded and run **independently of the sponsor** or other opioid manufacturers. Programs should also have built-in evaluation after they have been in place for a certain period of time.

Controls on opioid promotion:

The TGA should tighten controls on opioid analgesic promotion, including

- **Strictly overseeing** the promotion of new products, particularly for the first two years or until the potential for abuse has been evaluated.
- **Ongoing monitoring and restrictions** on promotion of products with high abuse potential or without abuse-deterrent properties.
- **Preventing advertising that** targets consumers through disease-focused campaigns (e.g. Mundipharma's 'Unlocking the Pipes'), particularly for products with high abuse potential or without abuse-deterrent properties.

5. REVIEW OF LABEL WARNINGS AND REVISION TO CONSUMER MEDICINES INFORMATION

Warnings

We strongly support adding boxed warnings to the **manufacturer's packaging** in addition to the PI, providing a repeated and highly visible reminder of the risks to consumers and practitioners. Warnings within the PI are hidden and repeated exposure, a key component to the effectiveness of warning labels,¹⁸ is unlikely. Pharmacy warning labels are often overlooked due to their placement and small font size, however, the TGA may like to consider use of Label 24 (For 3 days use only, can cause addiction), as previously used for codeine, in appropriate situations.

Warnings should also be prominently displayed on any promotional material for the drugs.

Recommended components in the warning:

- Information on the risk of dependence and overdose, on the limited evidence for long-term use in chronic pain, and the risks of long-term use.
- *'Long-term use (of a specified period) **should only be conducted under close medical care by a specialist.**'* This wording reduces the likelihood of hindering appropriate use.
- *'Caution is needed with other CNS depressant drugs.'*

Deprescribing

Approved Product Information should provide advice to clinicians on strategies for opioid deprescribing.

Return Unwanted Medicines program

In addition to raising awareness of the Return Unwanted Medicines program through changes to the CMI/PI, we suggest that **promoting the service through pharmacies** (e.g. through script backers, bag stuffers and signs/posters) or more widespread promotional campaigns is likely to have a greater impact. Targeting the promotional material to opioids may be beneficial.

7. POTENTIAL CHANGES TO USE OF APPENDICES IN THE POISONS STANDARD TO PROVIDE ADDITIONAL REGULATORY CONTROLS FOR STRONG S8 OPIOIDS

As previously mentioned, we suggest **restricting prescribing of fentanyl transdermal drug delivery systems, hydromorphone and high doses of other opioid analgesics** to appropriate specialists and authorised GPs where insufficient specialists are available.

As in the case of methylphenidate, add the following to the CMI/PI:

- Need for a comprehensive treatment programme
- Warnings on the limited evidence for efficacy and potential harms associated with the long-term use of opioids, and the need for regular review of treatment.

8. INCREASE HEALTH PROFESSIONAL AWARENESS OF ALTERNATIVES TO OPIOIDS (BOTH S4 AND S8 OPIOIDS) IN THE MANAGEMENT OF CHRONIC PAIN.

A note on tramadol

The S4 status of tramadol can create an illusion of safety and doctors should be educated that tramadol still carries an appreciable risk of dependence and misuse, both for its euphoric and sexual effects.¹⁹

OTHER SUGGESTIONS

The role of pharmacists

Medicine supply involves both prescribing and dispensing, and pharmacists have a key role to play in addressing problems associated with opioid analgesic use and misuse. Pharmacists are in a position to detect potential misuse by patients and inappropriate/over-prescribing by practitioners, yet often feel powerless to act. Pharmacists need the authority to deny or delay supply of opioid analgesics where there are concerns about inappropriate prescribing, and require support in discussing concerns with the practitioner. This involves developing agreed-upon protocols to be followed by both prescribers and pharmacists, and educational programs as to the role of the pharmacist aimed at pharmacists, prescribers and consumers.

Monitoring of use of other opioids following implementation of regulatory changes

There is a need for **close monitoring for substitution effects** (to tramadol, codeine, more accessible opioids analgesics, heroin and other synthetic opioids) following any change to availability, and a firm **plan** for dealing with such effects. Australia would do well to learn from the Canadian experience with fentanyl following the delisting of OxyContin from their formularies, and the growth in the use of alternative prescription opioids and heroin in the US after tighter hydrocodone scheduling.²⁰

Other factors

- Introducing **mandatory** Real-Time Monitoring of **prescribing and dispensing** in all Australian States and Territories.
- A review of the limitations of State and Territory-based regulations. For example, in NSW, an authority from the Ministry of Health is required to prescribe or supply an S8 drug, yet there is neither a requirement nor mechanism for pharmacists to confirm that this authority has been obtained.
- Ensuring adequate availability of accessible pain clinics and opioid dependence treatment programs.
- Destigmatising naloxone, thereby encouraging at-risk individuals (whether patients or otherwise) to be prepared.

We look forward to the outcome of this consultation.

Yours sincerely,

On behalf of the Pharmaceutical Policy Network, including:

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