In response to the TGA's invitation to comment on options for a regulatory response to the potential misuse of prescribed Schedule 8 (S8) opioids in Australia

To whom it may concern,

I am a hospital pharmacist who works closely with an Acute Pain Service in an Opioid Stewardship role. In my role, I commonly encounter the challenges associated with the current trends of opioid prescribing, such as instances of misuse, overdose, dependence, and opioid tolerant patients whose acute pain is very difficult to manage.

In response to the growing concerns associated with opioid use in the community at large, and particularly the with the impact that post-operative opioid use and discharge prescriptions may contribute, our hospital obtained funding for a pharmacist-led Opioid Stewardship Service to address incident trends, improve handover of plans made by the Acute Pain Service (to treating team and General Practitioner), and ideally reduce the contribution of our hospital to the problem of opioid use in the community.

The aspects of the Opioid Stewardship Service which are most relevant to this consultation are that:

(1) We promote the provision of plans to reduce and cease opioids on discharge from our surgical and orthopaedic wards, even if they include part-packs of medication (quantities less than full boxes).

(2) We provide pharmacist follow-up to outpatients who may be at high risk of prolonged use, misuse or harm to provide practical suggestions, encouragement, and advice to GPs to reduce and ideally cease opioids as soon as appropriate after discharge

(3) We provide specific disposal advice for excess opioids and discourage patients from retaining or sharing these medications with friends or family.

As a general suggestion to begin addressing opioid misuse originating from hospitals and hospital prescriptions, I believe a larger-scale application of Opioid Stewardship would be helpful in providing consistent resources and recommendations around opioid/analgesic use, and provide the opportunity for benchmarking between facilities, health services and states. With the success of Antimicrobial Stewardship in mind, and borrowing aspects of their goals, I believe Opioid Stewardship should be aimed at optimizing **analgesic selection**, dosing, route, and **duration of therapy** to **maximise a patients' pain management and function** while **limiting the unintended consequences**, such as the emergence of dependence, adverse drug events, and cost.

In addition to this, I would specifically like to respond to a few of the possible options put forward by the TGA:

- **Option 1:** Consider the pack sizes for strong (S8) opioids
    - I support this idea, particularly for short-acting opioids including Endone®/Oxycodone (usually packs of 20), Temgesic®/Buprenorphine (usually packs of 50), Tramadol and Morphine. There is evidence to suggest that a great deal (evidence varies between 40-60%) of short-acting opioids prescribed for acute pain does not get used (1, 2).
    - At our site, as part of the role of the Opioid Stewardship Service, we have promoted the prescribing of ONLY the quantity of opioid which is estimated to be required, not the full box or PBS quantity. Our Acute Pain Service commonly suggests quantities of 8, 10 or 12 Endone® on discharge, depending on the patients' requirements prior to discharge. This change in practice has resulted in a significant decrease in the average number of tablets supplied on discharge from our orthopaedic (from 15.4 tablets to 10.8, p=0.013) and surgical (16.6 tablets to 12.7, p=0.031) wards.
    - Additionally, evidence suggests that the longer duration of opioid therapy prescribed increases the likelihood of misuse and overdose (3). In light of this, packs sizes which facilitate shorter duration of therapy could help to reduce these opioid-related harms.

- **Option 3:** Consider whether the highest dose products should remain on the market, or be restricted to specialist/ authority prescribing.
    - I consider that the highest dose products should remain on the market, as there is a place for them for some patients, especially in the palliative care setting. For such patients, access to the most simple dose form (rather than multiple lower-dose tablets, or multiple patches) and to opioids in general is essential.
    - What is concerning to me, is that not infrequently we encounter patients in the acute pain setting who have chronic use of very high doses of opioids but have never had a review with a pain specialist and are managed solely through their General Practitioner. Such instances of this I have seen in the last year alone have included:
        - A patient with chronic knee pain (requiring surgery) taking Targin 70/35mg TDS (greater than the maximum approved dose of naloxone component). This is approximately 315mg oral morphine equivalent.
        - A patient with a unclear indication for Methadone 10mg tablets QID supplied 120 tablets at a time with no treatment authority and multiple ICU admissions attributed to her use of this medication which has continued to be prescribed by GP despite advice from hospital.
        - A patient prescribed Fentanyl 75microgram patch for chronic back pain/sciatica and red flags for abhorrent use. This is approximately 225mg oral morphine equivalent.
        - A patient awaiting knee replacement prescribed Hydromorphone SR 16mg mane/32mg nocte. This is approximately 240mg oral morphine equivalent.
    - I would consider that a forcing mechanism for referral to a specialist pain or palliative care service above a certain oral morphine equivalent dose (I have

seen the suggestion of doses greater than 120mg/day in a Queensland Health document), and a requirement for specialist approval to continue to prescribe these medications at high doses. However, for this to occur, there would need to be an accompanying increase in the accessibility of persistent pain services. For patients in our area, the nearest public pain clinic is 30-60km away, parking is expensive and public transport is nearly non-existent. The waiting list for this clinic can be years, and for the demographic of patients concerned, who are often severely affected by their pain and cannot work or drive, accessing this service even if they were accepted is unacceptably challenging.

- **Option 5:** Review of label warnings and revision to Consumer Medicines Information
    - As a pharmacist, I am sceptical of the impact that changing warning labels or packaging information would have on reducing misuse of opioids. I am also unsure which concerns would be most important to address on a warning label – this may vary for different indications and not be suited to a generic change in packaging.
    - Similarly, I am unsure that changes to the Consumer Medicines Information (CMI) may impact as they already contain substantial amounts of information which seemingly goes unread.
    - I am troubled by the general lack of understanding and concern that I have encountered in patients, even those on the strongest opioid medications. I suspect many patients don't have a grasp on the risk these medications can pose, even when used as prescribed. Some examples of this are patients I have encountered having had an unintentional polypharmacy overdose, both expressing they had no idea their analgesics and other medications could have such an effect.
        - Patient 1 – A 60-year-old woman with chronic back pain who was prescribed amitriptyline, diazepam, Endone®, Oxycontin®, pregabalin and temazepam, and had taken some extra doses of analgesia as her pain had worsened over previous weeks following a fall. She required intubation and ICU admission after being found unresponsive on her bathroom floor. She recovered and was able to be rotated to a less sedating regimen of pain medications but did express she genuinely didn't realise taking some extra doses of her analgesic medications could have such a catastrophic effect.
        - Patient 2 – Also a 60-year-old woman, who was routinely taking multiple sedating medications including Targin®, pregabalin, amitriptyline, mirtazapine and over-the-counter (OTC) promethazine. In the context of a severe headache, she took extra 'Mersyndol' (x 6 tablets) and Endone® (x 3 tablets). She too required an ICU admission with the diagnosis of opioid narcosis. This patient also recovered and expressed that she did not realise that her medications could all interact in this way.
    - My suggestion to help improve the provision of information and counselling provided to patients about their new opioid medications would be a more formal booklet similar to that used currently for warfarin counselling and

INR/dose monitoring. Warfarin requires extensive counselling as it is a high-risk medication which requires monitoring of therapeutic effect and can have severe adverse effects if used incorrectly. I see a parallel with opioid use. In the hospital setting (and potentially in the community), these warfarin books provide a clear, consistent and customisable outline around which a patient can be thoroughly counselled about the many complexities of warfarin use. I myself have found them to be an invaluable counselling tool. It is in a much more user-friendly/readable format than a typical CMI and includes information about risks and benefits of use, signs of overdose, and a section for recording which can be reviewed with a patient's clinician.

    - A similar format could be adopted for an opioid booklet, which may include: information about a patient's medication and dose (with pictures); the goals of their treatment; alternatives to opioids (simple analgesia and other measures like physiotherapy, psychology, online resources); a 'pain diary' to document doses used, pain scores and functional activity scores for review with their prescriber; management of side effects like constipation; **drug interactions with other sedating medications (especially OTC such as sedating antihistamines) and alcohol**; risks of short and long-term use; **signs of toxicity/overdose (and potentially discussion around access or use of OTC naloxone**); signs of dependence and addiction; and where to seek help for both chronic pain or concerns with dependence/addiction.

- **Option 8:** Increase health professional awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain.
    - The promotion of alternatives to opioids in the management of chronic pain to health professionals is essential. Opioids seem to be the 'easy' option when it comes to chronic pain management, when the interventions which are most likely to improve the patients' quality of life may include physiotherapy and psychology (eg. mindfulness training) (4).
    - Broader availability of multidisciplinary education would be helpful to address this lack of awareness. The ANZCA FPM Better Pain Management Modules provide a useful and accessible resource and learning tool to assess and manage patients in the biopsychosocial approach. Outside of this resource, availability of education is somewhat limited. From what I've been able to find, the University of Sydney provides a 2-week intensive multidisciplinary pain course for health professionals and also offers post-graduate studies in pain management. The intensive course is only available in Sydney, and both this and post-graduate studies come at significant expense to those who undertake and I expect would only be accessed by clinicians who already work in pain management. A more accessible and affordable option for attendance by General Practitioners, Nurses, Community and Hospital Pharmacists, Psychologists, Physiotherapists etc. could promote better awareness of the alternatives to opioids in the management of chronic pain.

- Refer to comment in Option 5 about unintentional overdoses – not only do patients need to be educated about the safe use of these medications, but so too do the health professionals need to be aware of the risks with multiple sedating medications (including benzodiazepines, TCAs, anticholinergics, opioids), aware of patient risk factors for complications such as Opioid Induced Ventilatory Impairment, and aware of risk factors for abhorrent use which may tip the risk/benefit balance against the use of opioids for particular patients.

Thank you for the opportunity to contribute to a consultation on this matter, and I look forward to seeing the changes which can be actioned as a result.

References

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