A Submission for Consideration Regarding Schedule 8 Medication Use/Misuse in Australia

To the Therapeutic Goods Administration,

My name is Daniel Mitchell. I am a registered nurse working at a major hospital in Melbourne, and I would like to share my thoughts and opinions on the topic of schedule 8 medications in Australia. I will start by addressing my concerns about these proposed restrictions, both from a personal and a professional perspective, and then I will continue by addressing each of the offered regulatory options.

When I became aware of the changing of codeine's status from over-the-counter [OTC] to prescription only, I was alarmed because it appeared to be a simplistic, one-size-fits-all "solution" that approaches a legitimate problem from an incorrect – and ultimately unethical – perspective. Specifically, it seems to be attempting to answer the question "How do we stop people overdosing on opioids?" when the question that I believe actually needs to be addressed is "Why are people taking so many opioids in the first place?"

I have many friends who are suffering from chronic pain conditions, including my partner, all of whom are already concerned about the decreased availability of medications that grant them the ability to function in society. These people – those with chronic conditions that cause pain – are your main users of opioid analgesia, and will be the most directly affected by whatever regulations you choose to enact.

While I understand that it's not always practical to obtain completely thorough information, I do not get the impression that anyone in the TGA – or anywhere in the Department of Health – has consulted anyone who has to rely on these medication classes for

their day-to-day functioning at any point. I find this to be an unconscionable oversight; it is grossly unethical to enact legislation or regulations that will directly affect the quality of life of others without consulting them, and I have not seen any evidence of such consultation anywhere. I value my friends, and I would hate to see the Australian government deliberately take steps to reduce their quality of life through well-meaning but misguided regulations, and blanket regulatory responses without consideration for the people it will actually affect.

As a registered nurse, my main professional concerns about any further restrictions on the availability of opioids are the potential ways in which it will increase the burden on hospitals and the healthcare system/society in general. Such burden increases include, but may not necessarily be limited to:

- Increased presentations from people suffering the symptoms of acute paracetamol or ibuprofen overdose/poisoning, due to chronic pain sufferers having to resort to increasing doses of OTC analgesia in an attempt to relieve their pain and regain the ability to function;
- Related to the above, increases in long-term incidences of further chronic conditions caused by long-term usage of analgesia (e.g. chronic liver damage from long-term use of paracetamol, or frequent gastrointestinal bleeding from long-term use of ibuprofen), which will further increase the burden on the healthcare system from preventable conditions;
- Increased presentations from people suffering from chronic pain conditions turning to hospitals out of pain-induced desperation in an attempt to gain access to the analgesia they used to be able to obtain from their GP, further increasing the burden on the hospital system;

- Increase in drug overdose presentations, as people with chronic pain conditions turn to illicit substances or black-market (and unregulated) opioids in an attempt to manage/control their pain.
- Related to the above, a potential increase in drug-related crime and underworld activity, as black market drug labs work to supply an increased demand, which will increase the workload of law enforcement;
- Decrease in general productivity of the workforce, both from the loss of previously-functional workers being forced to use leave on days when their pain is unmanageable, which will increase the cost to employers and businesses both through lost person-hour productivity and increased usage of sick leave;
- Increase in injuries, illnesses, hospital presentations, and deaths caused by people with chronic pain issues being preyed on by peddlers of "alternative medicine" (e.g. laetrile, homeopathy, Miracle Mineral Supplement);
- Related to the above, decrease in public trust in the healthcare system due to the (potentially justified) perception that it leaves people to suffer in pain without care.

My concern is that any regulatory or legislative change that isn't carefully and appropriately considered will cause one or more of these to occur, any of which will contribute to an increase in the overall burden of the healthcare system either directly or indirectly.

I appreciate that the TGA has prepared several different avenues of addressing this question, and I will take my time to address each one in turn.

1. **Consider the pack size for Schedule 8 opioids**

I recently had surgery for a minor umbilical hernia repair. The surgery was complication-free, and despite experiencing minimal pain I was given twenty 5mg oxycodone immediate-release tablets to take home. I ended up using none of them and ended up returning the entire unused packet to the pharmacy.

Considering the pack size of opioid prescriptions would prove useful in reducing the number of opioids prescribed in total, particularly in cases where acute surgery isn't expected to leave long-lasting pain effects. A reduced number of pills prescribed post-surgery would give a good indication of how well the surgery has progressed and whether the patient has experienced any complications that will require further investigation.

However, this option would only be appropriate for very short term management of pain issues (such as pain post-surgery from hernia repair or wisdom teeth extraction) and could be potentially used as a flag for further investigation should it prove insufficient. Prescriber education would be the best way to implement this approach.

2. Consider a review for the indications for strong opioids.

While this is a good idea, I don't think it should be done in isolation. Such a review should be performed in conjunction with research connected to Considerations 6 and 8; interlinking the studies of these three considerations will provide a significantly more comprehensive overview of pain management research and give both current and future legislations a significant and useful body of information to work from.

3. Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing.

Of all of the proposed considerations, I find this one the least appropriate.

Firstly, it will greatly increase the workload on specialists, who will now have to deal with an increase in patient load that they didn't have to concern themselves with before, on top of their regular patient load. This will increase specialist consult waiting times, which will potentially lead to one or more of the problems I outlined earlier in my submission.

Secondly, such a consideration is vulnerable to adjustment after implementation. If this regulation is in place, it would be trivial for someone to adjust the definitions or wording so that other, lower doses of opioid analgesia come under its umbrella, further shutting chronic pain sufferers out from accessing the healthcare they require. I understand that the doses the consideration is referring to are designed more for terminal oncology patients, but the potential for expanding such a regulation to other, lower doses of opioid is a risk that I find outweighs any potential benefits to such a regulation.

4. Strengthening Risk Management Plans for opioid products

Further education of prescribers and healthcare providers is always a good idea. However, I would insist that such educational programs require input from people with chronic pain conditions in order to be considered valid; since such programs will directly affect people with chronic pain conditions, it's only appropriate that they be generally consulted about programs aimed at educating prescribers about their pain conditions.

Such education will also need to take steps to prevent prescribers from falling into the trap of ignoring or disregarding a patient's experience of pain. This is a significant problem with many healthcare providers, and directly impacts the quality of healthcare received by people with chronic or mental health conditions, both ongoing and new-onset. These educational modules will need to ensure that prescribers actively listen to and act on a patient's concerns, and not dismiss them based on factors such as their gender, past medical history, or physical appearance.

5. **Review of label warnings and revision to the Consumer Medicines Information**

While increased information – and access to information – is good, enacting this consideration will require careful thought and writing to ensure that the warnings are actually understood by patients. Even then, just because the information is readily available doesn't mean that the information will be used or even accepted, as anyone who's ever had to argue with someone who is anti-vaccination can tell you.

I think this consideration would be best conducted in conjunction with Consideration 4 above; doing both will increase the education of both prescribers and the general public, and making sure the information is consistent through both areas will help with conversations about opioid analgesia.

6. **Consider incentive for expedited TGA review of improved products for pain relief and opioid antidotes**

If I were asked to support only one consideration, it would be this one.

Of all of the considerations the TGA has made available, this one is the most important. Increasing the options available for analgesia, especially for people with chronic pain conditions, can only be beneficial in the long run – it will be the most effective way to decrease the prescribing of opioids, and increase the options available to prescribers for pain management.

Conducting long-term research into alternative forms of analgesia, such as marijuana and kratom, will only prove beneficial to the healthcare system; as more options for the treatment of chronic pain become available, prescribers will be able to choose more

appropriate medications for their patients rather than resorting to opioid analgesia, potentially leading to improved quality of life for these patients and others.

Encouraging independent, government-funded research along these lines will ensure that research data is objective and not subject to manipulation by corporate interests. By expanding our understanding of other substances that have potential analgesic properties (and hopefully developing new medications based on that research), we will permanently improve the quality of healthcare available not just in Australia, but around the world.

If this consideration is not accepted and followed up by the TGA, I will be profoundly disappointed. I also find it concerning that this was *not* one of the recommendations that the Advisory Committee for Medications chose to focus on.

7. Potential changes to use of appendices in the Poison Standards to provide additional regulatory controls for strong opioids

This consideration is also one of the less practical ones and will, as I pointed out in my response to Consideration 3, unnecessarily increase the burden on specialist practitioners. This consideration is also the one that comes across as the most punitive towards people with chronic pain conditions, effectively punishing them for existing with a chronic condition by arbitrarily restricting access to medications they need. Any necessary education relating to this is likewise made redundant by adopting Consideration 4.

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

I am honestly surprised that the TGA and the Department of Health haven't already implemented this. This consideration pairs nicely with Considerations 4 and 6 above, and can be done with both currently available analgesia options (such as gabapentin or pregabalin)

and any future analgesics that are discovered or refined in the course of current and future research. Given the prevalence of conditions that can cause chronic pain, education on all aspects of long-term pain management should be a compulsory part of future prescriber training.

In conclusion, I find it most appropriate to professionally endorse the following four of the eight considerations as being the most appropriate to deal with the question about opioid analgesia raised by the TGA:

- Consider the pack size for Schedule 8 opioids
- Strengthen Risk Management Plans for opioids
- Incentivise research into non-opioid analgesia
- Increase prescriber education into long-term pain management

For the most comprehensive and useful results, I would personally suggest adopting all four of these considerations. It is my professional opinion that these considerations in conjunction will provide the most effective response to concerns regarding opioid prescribing, both in the short-term and in the long-term.

Regards,

Daniel Mitchell