Submission:

Prescription strong (Schedule 8) opioid use and misuse in Australia–options for a regulatory response

Please accept my formal submission regarding the regulation of high strength opioids. I discuss my view on each consideration.

The current situation today is the result of a focus on regulation, rather than innovation and investment.

Many of the options discussed here are still reflective of a culture to over-regulate rather than address real problems.

I thank you for providing the opportunity to submit a response.

Option 1: Consider the pack sizes for Schedule 8 opioids

Controlling the pack size prescribed by underwriting criteria through the PBS may at the point of prescribing prevent oversupply; it potentially may *slow* diversion practices. However, addictive behaviour through lies about pain thresholds may convince prescriber to prescribe the bigger pack size and will not prevent doctor shopping. Pain thresholds of patients are difficult to gauge and this is easily manipulated by patients who are addicted.

Pharmacies potentially may not stock smaller pack sizes. They may only stock the larger pack sizes, breaking them to supply smaller pack sizes but claiming the PBS benefit on the smaller pack whilst saving on cost. This may incur unnecessary PBS expenditure.

Therefore I don't believe this measure will be effective in dealing with the following main outcomes and/or drivers of opioid overuse:

- overdose resulting in morbidity or mortality
- tolerance, requiring higher doses of product being required to achieve analgesia, but with accompanying increases in adverse effects (including potential addiction)
- addiction, including following tolerance and through use at prescribed rather than excessive levels
- deliberate abuse, encompassing use of high doses of immediate release opioids and manipulation of 'abuse deterrent' dose forms
- overuse or inappropriate use

The above measure may have a limited effect in dealing with the following main outcomes and/or drivers of opioid overuse:

- Diversion of legally-prescribed product to others for abuse purposes.

A live and mandatory prescription monitoring service shared by all pharmacies would serve to regulate supply more effectively as supply intervals can be considered on the next dispense.

- Changing proprietary packs is therefore unnecessary.
- Pricing and stock structures of pharmacies and the PBS need not change.
- Prescribers, patients and pharmacists share accountability as there is live monitoring where the entire supply chain to patient is live and monitored.

I don't believe it is appropriate to dedicate tax payer funds to the up regulation of packet sizes as it is going to solve very little problems associated with addiction and morbidity. I would rather see those funds go towards education and preventative health and support services. Option one is an attempted Band-Aid solution to a deeper problem.

Option 2: Consider a review of the indications for strong opioids.

I feel this would be beneficial, mainly from a therapeutic standpoint and not so much from an addiction standpoint.

Studies and evidences for the use of opioids require review and distinctions must be made between statistically significant evidence for use (which is widely adopted by companies wanting product approval) vs therapeutically significant evidence (which is generally a higher bench mark of evidence for a medicines efficacy, but isn't as widely adopted).

Accepting and listing products on the PBS based on statistical significance benchmarks of data can result in poorer treatment outcomes and inefficient PBS expenditure as the patient might otherwise be using a product with better "therapeutically significant" data to support its use with a potentially better outcome.

I don't believe this measure will be effective in dealing with the following main outcomes and/or drivers of opioid overuse:

- Deliberate abuse, encompassing use of high doses of immediate release opioids and manipulation of 'abuse deterrent' dose forms
- Diversion of legally-prescribed product to others for abuse purposes.

I believe improving indications for opioid use would achieve a better outcome in relation to:

- tolerance, requiring higher doses of product being required to achieve analgesia, but with accompanying increases in adverse effects (including potential addiction)

If a patient is prescribed a product with an indication that is *therapeutically significant* to their condition rather than *statistically significant* – they are less likely to form tolerance or suffer adverse effects as the therapy is adequate, resulting in an improvement in the following outcomes and/or drivers of opioid overuse:

- overdose resulting in morbidity or mortality
- Addiction, including following tolerance and through use at prescribed rather than excessive levels
- Overuse or inappropriate use.

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

The reasoning for this option is to limit accessibility and therefore reduce morbidity associated with opioid use. The issue of restricting highest dose products to specialists has a few dimensions.

The first is the reality that necessary chronic pain treatment with opiates can lead to dependence and addiction followed by tolerance which will progress the patient up the analgesic scale. This will lead to addictive behaviour when it comes to seeking a prescription. These clients will bypass doctors that refuse to prescribe, or be an unnecessary burden on specialists. The clients will not only be claiming a PBS benefit at the GP, but also at the specialist and this will become a cyclical event for these chronic pain clients, and an added expenditure to the PBS.

The second issue is that today many patients are also treated like customers that must be appeased. Patients not prescribed what they are after will visit another doctor who may prescribe, or they may make a complaint or blatantly lie about their pain. This will only result in more referrals to specialists for those chronic pain patients who have progressed up the analgesic scale.

The question then becomes, the patient is at the specialist – what now? More than likely they will be prescribed their analgesic request as more often than not the source of the pain cannot be extinguished – so the need for analgesia is permanent and provided, making the proposition to restrict supply to specialists meaningless.

It's also important to consider the reasoning and indications for chronic pain prescribing in the case of non-cancer patients, which ties into the issue of option 2. If doctors are empowered to deny patient unnecessary narcotics or prescribe withdrawal ***without*** fear of complaint or litigation – then prescribing may be more ethical and appropriate. This requires a cultural shift in the way the community perceives pain, deals with pain, and has their pain treated, as well as their addiction. Too often a consumerist quick fix ideology accompanies a patient in pain on their visit to the specialist or GP. This cultural issue requires education in order to be corrected, and therefore is not solved by measures proposed in option 3.

Therefore, restricting highest dose products to specialists would not address any of the outcomes and/or drivers of opioid overuse. Patients seeking higher strength products are most likely to have an existing dependence and addiction even if the use is legitimate because addiction is not an optional side effect.

I believe high dose products have a place in medicine. What is lacking from the market space is adequate support services and step down therapy support. The CPOP evidences this, as many remain addicted to opioid substitutes and often relapse and cycle in and out of tax payer funded programs.

A mandatory and guided step down regimen with strict dates should be implemented and documented by any prescriber providing high dose analgesic therapy, and subject to audit, and if necessary hospitalised withdrawal in the case of serious addiction or dependence.

These measures may then require the involvement of a pain or addiction specialist, referred by a GP *as a function of the GP's professional judgment* ***rather*** than a blanket regulation. Holistic integration is also required in the form of community support, counsellor and spiritual (not religious) support and possibly relocation for those seriously addicted. I feel those measures would *reduce* the following outcomes and/or drivers of opioid overuse:

- Addiction, including following tolerance and through use at prescribed rather than excessive levels
- overuse or inappropriate use
- Diversion of legally-prescribed product to others for abuse purposes.
- Deliberate abuse, encompassing use of high doses of immediate release opioids and manipulation of 'abuse deterrent' dose forms.

Option 4: Strengthening Risk Management Plans for opioid products

I don't see any problem in reviewing risk management plans to ensure they are reflective of best practice principles. The benefits of this would tie in well to address issues I have raised in the discussions about Options 3 and 4.

RMP contains an education component for health providers rather than an authoritarian blanket regulation. I therefore believe it will be more far reaching and have a better impact on prescribing decisions as there is consideration of patient safety according to sound safety data, in preference to following a restriction in fear of disciplinary action by overzealous regulators.

Option 5: Review of label warnings and revision to the Consumer Medicines Information

Review is warranted and the warning of dependence and addiction should be plain, clear and transparent and communicated at all levels for all uses. This risk not only needs to be included on labels and CMI's, but *must* be verbally communicated by doctor and pharmacist. It's important to note that most patients don't adequately read written information.

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

Review of emerging or current alternative products should be pursued. The recent OTC up-schedule presents the challenge of recommending alternative products.

In the pharmacy (without delving into the retail dilemma and how that has perverted healthcare), pharmacists are faced with an ethical dilemma of companion selling or recommending products to support pain relief – quite often the evidence base of these products is questionable. Now with codeine up-scheduled and restricted, alternatives such as 'tumeric' or 'PEA' or sAME, and T.E.N.S devises are alternatives that lack adequate evidence that a business owner may expect staff to recommend, especially if anti-inflammatories are tried or not appropriate.

In light of the above dilemma, the more common recommendation from the pharmacist to these patients will be to refer patient to the doctor for the patient's standard codeine product. This will now result in greater GP visits and more PBS benefit claims - in a climate where the government wants to save on the PBS this was an ironic move – just another short sighted money saving exercise that will cost in the long run.

Expedited alternatives or NCE's should be a priority over a regulation such as a pack size change (for reasons explained in Option 1 discussion). Expediting formulations that prevent or reduce abuse is a sound option.

Medical Marijuana regulation should be reviewed again to grant more accessibility as a pain relief alternative. The bureaucracy existing between states for this alternative is dizzying. The projected 10 billion dollar market means there is growth and a viable alternative. Supply chains are established and market leaders in Australia are positioned to deliver – it is an expensive regulatory culture that has slowed the market development and accessibility of NCE's and Cannabis, in preference for cheaper established opiates. Expediting research and approvals in this area should be an option for consideration and Australia is well positioned to do this, as a leader

Option 7: Potential changes to use of appendices in the poisons Standard to provide additional regulatory controls for strong opioids

This option feels is another way to enforce up-regulation of stronger opiates, to achieve a proposition similar in option 3.

If restrictions are to be placed on higher strength opioids that target specific populations, perhaps this could be done by distinguishing between fast and slow metabolisers. With this there is guidance on prescribing based on pharmacokinetics, rather than arbitrary restrictions.

A proposition would be introducing mandatory metabolism testing of a patient who may require higher strength opioids – which would guide dosage strength and frequency. This would improve the following outcomes and/or drivers of opioid overuse:

- overdose resulting in morbidity or mortality
- deliberate abuse, encompassing use of high doses of immediate release opioids and manipulation of 'abuse deterrent' dose forms
- overuse or inappropriate use
- tolerance, requiring higher doses of product being required to achieve analgesia, but with accompanying increases in adverse effects (including potential addiction)

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

For similar reasons expressed in options 4 and 5, education is key. However, as stated in discussion of option 6 – NCE's require expediting. In the pharmacy setting, it's all good discussing alternatives for pain but if we are in the realms of strong opioid's discussing turmeric or fish oil isn't realistic or appropriate.

There is plenty of training on opioids and it should be better circulated; agreed. Where I see most of these trainings falling short is the discussion of alternatives, and this is because not many suitable alternatives exist because NCE's for pain relief have not been a focus. Old anti-epileptic classes that share a wide variety of indications may not be appropriate as they carry their own adverse effect profiles making them less desirable in many cases.

This country needs to side step the temptation to over regulate and instead invest in the future of opioid alternatives.

Advisory Committee Recommendations commentary

The introduction of smaller pack sizes for strong opioids that may be prescribed when short-term use is required, such as for pain relief after surgery.

For reasons discussed on options 1, this is a waste of time and resources.

A review of the approved indications for S8 opioid medicines and align them to current clinical guidelines

As discussed in option 2, this is great as it aligns therapeutic reasoning with prescribing outcomes. Indications must be based on *therapeutic significance*.

Work with the Health Technology Assessment and Access Division of the Department of Health to consider PBS prescribing restrictions, such as smaller quantities and the requirement for specialist medical review of non-cancer pain patients prescribed opioids for extended periods

For reasons discussed in options 1 and option 2, this is a waste of time and resources. As discussed in option 7 – allow opioid metabolism testing to guide the therapeutic decisions of high dose opioid prescribers.

Work with clinical colleges to educate prescribers on judicious use of opioids, treatment de-escalation and the use of non-opioid pain relievers.

There needs to be more investment and support post opioid use, addiction, de-escalation, and the expediting of NCE's.