



Consumers Health
Forum **OF** Australia

SUBMISSION

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

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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems

There has been much media attention to the ‘opioid crisis’ both here and overseas, most notably in the USA. Many of the submissions on the recent rescheduling of codeine products highlighted the problems around prescription opioids. Unlike the low dose over-the-counter codeine products the evidence supports that strong opioids are an important tool in dealing with severe acute pain from trauma and surgery and for pain associated with cancer and some other conditions. The problem seems to be that its use has become too widespread and it is often used for too long or for conditions for which the evidence of efficacy is weak. There is also a growing problem of misuse and a failure to recognise dependency and addiction.

We agree with the consultation paper’s contention that ‘any regulatory response must not unduly restrict informed, rational prescribing of opioids’ but think the current situation shows that we need to recalibrate the use of opioids to ensure that prescribing is best practice and in patients’ best long-term interests. In many ways the opioid problem is in part an outcome of the lack of a comprehensive national approach to pain management and the failure to implement the National Pain Strategy. It is hardly surprising that, in the absence of alternative pain management services, consumers and health professionals have turned to the most available opioids.

We need some reforms and the consultation identifies some possible regulatory options. Any such regulatory reform needs to be part of a more comprehensive approach to pain management. We are urging all governments to support the review and implement the National Pain Strategy to ensure that people have a real choice when moving off opioids and health professionals and consumers know there are alternatives that people can access as and when they need them. We have also joined the call for the national roll out of electronic recording and reporting of controlled drugs as an important component of reducing misuse and abuse of prescription opioids.

We need more education of both health professionals and consumers about both the benefits but also the risks of opioid use. Health professional education is covered in Options 4 and 8 of the consultation paper but the consumer education component is missing. Consumers need to understand why they are being prescribed opioids, what it is for and how to use it responsibly. They also need to understand the risks of misuse and prolonged use.

There needs to be a broad community conversation about this issue and we support pain Australia’s position in their submission to this process that they are ideally placed to assist with that conversation. Consumers can be effective agents for change and need to be part of the conversation and involved in all elements of the reform package.

Options

Option 1: Consider the pack sizes for Schedule 8 opioids

CHF supports the requirement on manufacturers to make smaller pack sizes available for treatment of people with acute pain. These would be in addition to the larger packs as currently available.

This should be a priority action as it would make a significant contribution to reducing the availability of opioids and ensuring people do not use them for longer than needed. A smaller size pack would make it easier for prescribers to give 1-3 days' supply with the patient then needing to go back to the doctor if they needed more. That would then trigger an assessment of ongoing pain and allow early discussion of alternatives.

We know from work done by the Return Unwanted Medicines (RUM) Project and Griffith University that people do keep medicines in their cupboard and that 75 per cent of them keep them 'just in case they need them in the future'¹. The move to smaller packs would reduce the possibility of people storing the opioids in their medicines cabinets for later use. This improves safety with fewer opioids being available and it reduces inappropriate use.

We accept that would need to be clear delineation of indications between the small and large packs and that there may need to be changes to the PBS listing. It also needs a prescriber education process to encourage them to only prescribe the smaller packs, especially on discharge from hospital. Consumers may initially be resistant to the move to give smaller amounts initially and this will require better conversations as part of discharge planning to explain what and what other pain management is available after the opioids a course is complete.

We can see no disadvantage to consumers of moving to this approach and believe the benefits of moving to make smaller packs available outweigh the costs.

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

CHF supports this and believes that the review is overdue and so should be commissioned as soon as possible.

For quality use of medicines, it is important that use of medicines is based on the best current evidence available and that indications are consistent with clinical guidelines. The review needs to be comprehensive and look at pain associated with cancer and other non-cancer pain. The medical colleges would need to review their clinical guidelines to making sure they reflect best practice, are evidence based and meet a broad range of needs. The indications can be lined up with those guidelines.

Option 4: Strengthening Risk Management Plans for opioid products

CHF supports reviewing risk management plans to ensure they reflect current best practice in opioid management prescribing and management of risks.

The risks involved with using opioids means that there should be risk management plans in place, even though many were registered before RMPs were required.

¹ A. Wheeler, E. Bettington, F Kelly, J Spinks Health Checks; what should you do with your unused medicine viewed at <https://theconversation.com/health-check-what-should-you-do-with-your-unused-medicine-81406>

Education on pain assessment and management, including opioid prescribing should be a mandatory component of all Continuing Professional Development programs. This would mean that practitioners in need of additional support and those identified as ‘at risk’ by the Medical Board of Australia could be directed to undertake the training.

Whilst the risk management plans are the responsibility of the sponsors there is a need to not leave all the training to industry. The responsible clinical groups and medical colleges should all be involved in the development of the education and training. Whilst industry and clinical groups continue to develop their own materials this needs to be done in a collaborative way as it is important that there is consistency of message.

CHF agrees with the list of areas that any such education and training should cover as outlined in the consultation paper.

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

CHF supports revising the Consumer Medicines Information(CMI) and reviewing the label warnings as important parts of consumer education to ensure safe use of opioids. The work on this should be done in close consultation with consumers and industry.

The CMI is an important tool to help people use medicines safely and get the maximum benefits from them. CHF supports improving the CMI and including warning about prolonged opioid use within it. Unfortunately, we know many people either don’t receive the CMI or don’t read it. We need to tackle that if the opioid warnings are to have any impact on people’s behaviours.

For the warnings to have an impact they need to be at the top or beginning of the CMI as We have been part of a working group convened by Medicines Australia looking at redesigning the CMI with view to making it more user friendly. We note the work done on the product Information and would like to see TGA take some leadership over redesigning the CMI to improve its uptake.

There is also a need to look at ways people access the CMI and to try to encourage them to read it. The mobile app is a step in the right direction on this, but people need to know about it and the documents are still not presented in a more consumer friendly way. The Pharmaceutical Society of Australia and the Pharmacy Guild, could also do more to improve provision of the CMI with new medicines. In our submission to the recent Review of Remuneration and Regulation of Community Pharmacy ² we highlighted the inconsistency of approach to this with some pharmacists always giving some information, others offering it and others having a notice at the dispensing counter telling consumers to ask for it. As part of addressing the provision of CMIs pharmacist could be required to read out the warnings to ensure the consumers has heard the information.

Putting a clear warning about opioids on the labels seems an obvious way to tackle the problem and alert people to the danger. However, we know that there is already a lot of information on the labels and that many people do not read them. We are suggesting there needs to be a review of the labelling which involves consumers to look at how the warnings could be incorporated and what is the most effective way to get the message across.

² CHF 2017 Submission to the Review of Remuneration and Regulation of Community Pharmacy at www.chf.org.au/publications/policy/submissions

We also think that there should be information about the RUM process handed out or brought to consumers attention with all prescriptions but particularly opioids to make it clear to people that they should not keep any unused medicines.

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

CHF strongly supports this option and believes this work should be extended to include a program of consumer education.

This option is in line with the National Pain Strategy which calls for professionals to work with people with pain to have access to best-practice evidence-based assessment and care. This option should be implemented along with Option 4 which looks at strengthening the risk management options for opioids. Any professional education on use of opioids should include an understanding of the alternatives. This program of awareness needs to be led by the medical colleges, some of which are already looking at their guidance on the use of opioids and chronic pain management. We note that there are resources already available including the NPS Medicine resources, the Better Pain Management learning modules from the Faculty of Pain Management.

To reduce opioid prescribing doctors, need to be aware of the alternatives and be prepared to work with their patients to implement them. To do this they need to be sure that the alternatives are available. It is not good enough to take people off opioids without being sure that the alternatives, particularly the non- pharmacological ones, are available to them. The awareness program therefore needs to include information on what is available in a given area and how a consumer might access them. This can then form the basis of a constructive conversation between doctor and patient to develop a pain management plan.

There needs to be more consumer education about the alternatives to opioids for chronic pain management. This conversation has started with the work done as part of the community awareness campaign for the rescheduling of codeine. It is important that this is built upon so that fewer consumers expect opioids and are receptive to trying alternatives. Any further work needs to be co-designed with consumer to make sure it gives consumer the information they want, in the way they want it.

Other Options

The following three other options in the consultation paper could all contribute to better use of opioids, but we do not see them as a priority for action.

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

- We do not support removing the highest dose products from the market. This would not be consistent with the notion that strong opioids have a role in managing severe acute pain and pain experienced by people with cancer and some other conditions.
- It would be premature to take such action before the impact of the other initiatives is measured.
- Both suggestions under this option would impose undue restrictions on access to opioids and are not in line with the objective of having informed rational prescribing of these drugs in the interests of the patients.

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

- CHF supported the introduction of the expedited pathway for new medicines and so supports its use for pain relief and opioid antidotes where they fit the criteria for the new pathway.
- We do not see the case for additional incentives for such medicines, particularly as there do not appear to be a significant number in the pipeline.

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

- CHF would support more work being done on how the Poisons standards could provide additional regulatory control. However, it could take a long time and we do not think this is a priority at this time. Any such review should wait until the impact of the some of the other options, if implemented, can be evaluated.

Conclusion

CHF believes that there is scope for some regulatory reforms to make a positive contribution to reducing the misuse and abuse of strong opioids and contributing to better pain management for consumers. Many of the options presented in this consultation paper are consistent with the National Pain Strategy and for them to be effective the Strategy needs to be fully implemented.

To be successful the reforms need to be co-designed with consumers actively involved in the development and the design of any initiatives and communication package that goes with them.