

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: PSAB.Communications@tga.gov.au

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

The Health Care Consumers' Association (HCCA) was incorporated in 1978 and is both a health promotion charity and the peak consumer advocacy organisation in the Canberra region. HCCA provides a voice for consumers on health issues and provides opportunities for health care consumers to participate in all levels of health service planning, policy development and decision making.

HCCA involves consumers through:

- consumer representation and consumer and community consultations;
- training in health rights and navigating the health system;
- community forums and information sessions about health services; and
- research into consumer experience of human services.

HCCA is a member based organisation and for this submission we consulted with our members through the HCCA Health Policy Advisory Committee and more broadly through our membership and other consumers with an interest in these issues. We also received input from both Pain Support ACT and the Women's Centre for Health Matters.

Thank you for the opportunity to put forward consumer views on regulatory options to address opioid use and misuse in Australia.

Yours sincerely

Darlene Cox

**Executive Director** 



#### **HCCA Submission to the**

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

Consultation Paper from the Therapeutic Goods Administration

Submitted 9 March 2018

Contact: Darlene Cox Executive Director 02 6230 7800

#### Contents

| Executive Sur          | mmary   | 1     |
|------------------------|---|-------|
| Recommend              | ations  | 2     |
| HCCA respon            | se to options   | 3     |
| General Com            | nments  | 4     |
| People v               | with chronic pain in the ACT  | 4     |
| The opioid crisis      |   | 4     |
| The driv               | vers behind increased misuse  | 5     |
| Doctors                | shoppingshopping  | 5     |
| Real tim               | ne prescription monitoring for medicines  | 6     |
| Specific com           | ments on regulatory options presented by TGA  | 7     |
| Option 1               | Consider the pack sizes for Schedule 8 opioids  | 7     |
| Option 2               | Consider a review of the indications for strong opioids   | 10    |
| Option 3 restricted    | Consider whether the highest dose products should remain on the market to specialist/authority prescribing                      | -     |
| Option 4               | Strengthening Risk Management Plans for opioid products   | 13    |
| Option 5               | Review of label warning and revision to the Consumer Medicines Informat   | ion14 |
| Option 6 opioid ant    | Consider incentives for expedited TGA review of improved products for paidotes  |       |
| Option 7 regulatory    | Potential changes to use of appendices in the Poisons Standard to provide controls for strong opioids                           |       |
| Option 8<br>Schedule 4 | Increases health care professional awareness of alternatives to opioids (both and Schedule 8) in the management of chronic pain |       |
| Concluding re          | emarks  | 19    |
| References             |   | 20    |

#### **Executive Summary**

As the peak member-based consumer advocacy organisation in the ACT, the Health Care Consumers Association (HCCA) has a longstanding interest in medicines and their use by consumers in the ACT. We know that medicines are one of the most common treatments used in the health care system, and that appropriate use can often lead to significant improvements in health<sup>1</sup>.

HCCA recognises that there will always be some misuse of such medications, and that the misuse of opioids is rising. However, many people in our communities use opioid medications to good effect, for relief from acute or chronic pain. HCCA seeks to ensure that those who need pain relief have access to appropriate medication or treatment in accordance with our National Medicines Policy.<sup>2</sup> Unfortunately, this is not always the consumer experience in the health care system.

Consumers want their issues with pain to be heard and understood by their health professionals. Ideally, consumers need this to be a conversation and process of shared decision making.<sup>3</sup> This requires health professionals to understand the needs of consumers, and then in collaboration choose the most appropriate treatment/s from the range of medication and other non-medication pain relief options available. As an organisation we are working to improve health literacy which will help spark these conversations and encourage collaboration. Nonetheless, we need our health professionals to have at their fingertips an evidence-based 'toolbox' of the options for pain management.

HCCA's consultation with our members demonstrates that there are diverse consumer views on the question of how to best regulate strong prescription opioids. This diversity reflects the wide variety of health conditions for which opioids are indicated, and the diverse situations of health consumers including in terms of their ability to access and afford health care services.

In responding to the options and making the recommendations HCCA seeks to recognise this diversity of consumer perspectives, situations and priorities.

<sup>&</sup>lt;sup>1</sup> Professor Libby Roughead, Dr Susan Semple, Ms Ellie Rosen Feld, Literature Review: Medication Safety in Australia, Australian Commission of Safety and Quality in Health Care, August 2013. https://safetyandquality.gov.au/wp-content/uploads/2014/02/Literature-Review-Medication-Safety-in-Australia-2013.pdf [accessed 20 February 2018]

<sup>&</sup>lt;sup>2</sup> National Medicines Policy, Australian Government Department of Health and Ageing, 2000. http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/\$File/NMP2000.pdf [accessed 20 February 2018]

<sup>&</sup>lt;sup>3</sup> Shared Decision Making, Australian Commission on Safety and Quality in Health Care <a href="https://www.safetyandquality.gov.au/our-work/shared-decision-making/">https://www.safetyandquality.gov.au/our-work/shared-decision-making/</a> [accessed 27/02/2018]

#### Recommendations

To protect consumer rights and interests in the safe use of opioids in Australia, HCCA recommends that:

- 1. Work continue developing and implementing national real-time prescription monitoring for medicines<sup>4</sup>, which will assist prescribers and uphold safety for consumers
- 2. A broader education campaign be launched to encourage health practitioners who work with consumers needing pain management to adopt a "tool box" approach, (i.e. being aware of and making use of the wider range of useful and evidence-based pain management options). These include the most effective use of opioids and other non-opioid medications, as well as alternatives to medication such as multidisciplinary care, rehabilitation strategies, pain and self-management education. (refer to option 8)
- 3. Consumer access to appropriate pain is given more consideration. Restricting who can prescribe high dose opioids will mean that those who really do need these medicines may find it very difficult to access them. For instance, consumers living in rural and remote areas [or even outer metropolitan localities] may face difficulties in attending specialist appointments given:
  - a) their condition, such as a terminal illness,
  - b) their access to transport, and/or
  - c) the availability of appropriate specialists in their locality (refer Option 3 and Option 7).
- 4. The TGA explores undertaking a full cost-benefit analysis of options under consideration with a focus on identifying any potential unintended negative outcomes of investment in each of these areas.

<sup>&</sup>lt;sup>4</sup> Media Release: National approach to prescription drug misuse, 28 July 2017. http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt071.htm [accessed 26/02/2018]

#### **HCCA** response to options

- **Option 1.** HCCA supports the proposal that sponsors should register and make available small pack sizes, to assist prescribers and dispensers to provide more appropriate amount of opioid medication to manage acute pain, while maintaining larger pack sizes for those experiencing chronic pain. However we note that a 3 day pack may be slightly too short even for circumstance of acute pain.
  - HCCA is generally supportive of wider prescribing of smaller pack sizes, when this is clinically indicated. However, prescribing should occur in the context of shared decision-making between clinician and consumer to ensure that consumers receive pain management assistance that meets their needs.
- **Option 2.** HCCA supports a review of indications for S8 opioids to ensure they are aligned with current evidence-based clinical practice.
- **Option 3.** HCCA does not support Option 3. HCCA is concerned that Option 3 would reduce consumer access to medicines they need.
- **Option 4.** HCCA has no specific comment on this option.
- Option 5. HCCA is broadly in favour of Option 5, as additional packaging warnings may support informed choice about medication use. However, HCCA recognises that some additional warnings (depending on their wording) may conflict with advice and could appear to consumers to undermine the judgement of their prescribing clinicians. It is important that prescribing doctors have ample opportunity and the skills to discuss the benefits and risks of medications with consumers, in the context of shared decision-making about treatment.
- **Option 6.** While HCCA has no specific comment with regards to Option 6, it is likely that consumers and health professionals would welcome any new viable alternatives to opioids for strong pain relief.
- **Option 7.** In relation to Option 7, HCCA is concerned that restricting who can prescribe certain medicines will adversely impact on consumers' access to necessary medicines.
- **Option 8.** HCCA is supportive of Option 8. There is clearly a place for opioid therapy for some patients in the 'toolbox' of pain management, but the key principle should be to increase the broad knowledge and understanding of health professionals, along with consumers, in treating pain with the full range of therapeutic options available (both pharmacological and non-pharmacological).

#### **General Comments**

#### People with chronic pain in the ACT

In 2017, HCCA undertook a research project "Consumer experiences and expectations of General Practice and After-Hours Care in the ACT". Approximately sixteen percent of over 1000 respondents to an online survey indicated that they experienced chronic pain.<sup>5</sup>

Unsurprisingly, the self-rated health status of these respondents was generally much worse compared to the National Health Survey Data 2014-15. This suggests a treatment gap for those with chronic pain in the ACT. This finding is consistent with the strong evidence that many people with chronic pain do not receive adequate care<sup>6</sup>. An improved approach to pain management nationally will better meet the needs of people living with chronic pain. While opioids alone are not the answer to chronic pain, they remain an important part of the picture of pain management.

Fortunately, about 90% of those with chronic pain indicated that they had a regular GP, and 85% reported that their GP was very likely to support them in self-management, which was consistent with the more general survey findings of those with any chronic condition. These findings are indicative of the important relationship between patients' and their GPs.

We also asked where, other than their GP, these respondents turned for health information. A large majority (73%) of respondents with chronic pain identified their local pharmacy as a top source of health information. These findings highlight the trust placed by consumers in the health information received from pharmacies.

#### The opioid crisis

HCCA feels that the discussion paper was so focused on the 'opioid crisis' that it lacked information on how opioid medicines can play a useful role in short-term pain treatment, or when carefully managed, in helping those with long-term or chronic pain. For example, opioids can be used initially in the post-operative period as a means of helping people regain initial mobility and functionality, then tapered out gradually at the appropriate time to enable a greater focus on the other strategies that help. Consumers told us:

As a chronic pain sufferer, I rely heavily on opioid medication in order to improve my already poor functional capacity.

...they {opioids] are also helpful for a large and growing subset of individuals that suffer from chronic pain.

There was also an emphasis in the discussion paper on treating particular conditions (e.g. cancer vs acute pain vs chronic pain) rather than treating the individual consumer. The risks of dependency increase with the dose and length of time the opioid

<sup>&</sup>lt;sup>5</sup> The survey respondents were self-selected and thus are not fully representative of the ACT population.

<sup>&</sup>lt;sup>6</sup> Pain Australia. Access to Pain Management, A Fundamental Human Right. Available at: <a href="http://www.painaustralia.org.au/improving-policy/human-right">http://www.painaustralia.org.au/improving-policy/human-right</a>. [accessed 1/3/2018].

medication is taken, regardless of the condition(s). There are strategies that can be used to manage or reduce the risks of dependency in patients for whom opioid treatment is considered to be appropriate.

#### The drivers behind increased misuse

A significant concern about the discussion paper is that the 'misuse of opioids' section fails to examine all the drivers behind the increase in misuse. Some evidence is presented around the rising rates of opioid prescribing and overdose in Australia, along with coronial reporting revealing the increasing contribution of pharmaceutical opioids in drug-related deaths. However, there is no real evidence presented as to whether the rise in the misuse of pharmaceutical opioids is due to those individuals who have been prescribed the opioids, or by individuals who have obtained the pharmaceutical drugs illegally. The consultation paper makes it clear that not all overdoses result from prescriptions – it is important to keep in mind that around 27% of the deaths involving opioids included those from *non-prescription* sources (p.6 of the consultation paper). Regardless, it is important for safety that opioids are prescribed appropriately in order to minimise the risks of diversion.

We believe that the greatest influences on consumer access and use of prescribed pharmaceutical opioid medicines is likely to result from:

- the clinical assessment and shared decision-making process undertaken between the consumer and their health care professional(s);
- the powers vested in the states and territories to regulate (in various ways)
   who can prescribe opioids, to whom, and in what quantities; and
- the operation of the PBS in making medicines affordable through public subsidy, and the circumstances in which those public subsidies may be made (such as the quantities that may be made available and for what therapeutic conditions the medicine might be subsidised).

In addition, pharmacists dispensing medications have a duty of care to all patients in promoting the quality use of medicines through their processes that aim to ensure that consumers receive the right medicine, in the right dose, at the right time, and that medicine interactions and adverse events are minimised.

#### **ACT Regulatory Controls**

The ACT is fortunate to have a number of regulatory controls in place that assist in reducing the risks from opioids (and other Schedule 8/controlled medicines) in our jurisdiction. This includes the ACT's Controlled Medicines Prescribing Standards<sup>7</sup> to guide and streamline approvals by the Chief Health Officer for low-risk use of Schedule 8 medicines, and providing stronger criteria for applications for higher risk uses of Schedule 8 medicines.

The ACT has also implemented the Drugs and Poisons Information System (DAPIS)

<sup>&</sup>lt;sup>7</sup> Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2018 (No 1) <a href="http://www.legislation.act.gov.au/ni/2018-77/current/pdf/2018-77.pdf">http://www.legislation.act.gov.au/ni/2018-77/current/pdf/2018-77.pdf</a> [accessed 9/03/2018]

to record and monitor Schedule 8 medicines supplies and approvals. However, without a national real-time monitoring system data cannot be linked across jurisdictions.

#### Real time prescription monitoring for medicines

While now out of date, the National Pharmaceutical Drug Misuse Framework for Action 2012-1015, as mentioned in the discussion paper, recognised the importance of real time monitoring of the supply of opioids in the community as a priority area for action. The Hon Greg Hunt MP, Minister for Health, announced in July 2017 that the Australian Government would invest over \$16 million to deliver the national roll-out of real time prescription monitoring for medicines to directly address the needless loss of life from misuse of these drugs<sup>8</sup>. HCCA supports the establishment of such a system to address these issues and help protect consumer access for those who need opioids prescribed as part of their pain management plan. The ACT's system, along with a few other jurisdictions who also have systems in place for monitoring prescribing and dispensing, would be more effective if data could be linked in with a national system.

Finally, while the consultation paper considers the cost of the misuse of opioids more broadly on society, none of the regulatory options presented for consideration appear to have been informed by cost benefit analysis. A more rigorous analysis of impact for each of the regulatory options should draw out whether any could potentially lead to perverse outcomes or significant unintended consequences.

<sup>&</sup>lt;sup>8</sup> Media Release: National approach to prescription drug misuse, 28 July 2017. http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt071.htm [accessed 26/02/2018]

#### Specific comments on regulatory options presented by TGA

# Option 1 Consider the pack sizes for Schedule 8 opioids Require sponsors to register and make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28-day) for treatment of people with chronic pain due to malignancy.

- HCCA supports the proposal that sponsors should register and make available small pack sizes. However, we note that
  - a three-day pack may be slightly inadequate in some circumstances, and
  - o larger packs will still be needed in some circumstances.
- HCCA generally supports wider prescribing of smaller pack sizes, when
  - o this is clinically indicated and
  - occurs in the context of shared decision-making between clinician and consumer.

This ensures that consumers receive pain management assistance that meets their needs.

#### Reasons for introducing smaller packs

HCCA consumer feedback suggests that, even though it is currently possible, prescribers rarely prescribe less than the PBS opioid pack size for acute pain, such as post-operative analgesia, or pain due to a broken bone. One consumer commented:

For one of the most commonly prescribed opioids following surgery (oxycodone 5mg tablets – Endone®), patients are discharged with 20 tablets (or a prescription to obtain the tablets at a community pharmacy) with the instructions to use the tablets when necessary for up to three days or so. Twenty tablets are likely to be far in excess of most patients' needs in this acute condition. On face value, then, the introduction of smaller pack sizes of opioids would seem a sensible idea.

A few consumers also mentioned that they felt dentists often only need to prescribe appropriately small amounts of pain medication for acute dental or post-surgical pain.

#### **Advantages**

Having smaller pack sizes available would help educate prescribers about each consumer's needs in terms of frequency and dose. Other advantages of having a smaller pack size (or fewer tablets) available are

- potentially reducing the risk of over-dosage,
- possibly reducing costs, and
- minimising the risk of opioid medicines being used by those other than the patient for which it was prescribed.

#### **Disadvantages**

The downside to smaller pack sizes is that if not appropriately prescribed, they could lead to consumers needing more GP or specialist visits, incurring greater costs and potentially access difficulties after surgery or an injury. The Women's Centre for Health Matters told us that their research<sup>9</sup> found that:

Affordability was a barrier to accessing services for younger women in the ACT, and therefore it is important to ensure that access to medications such as opioids are not hindered by restrictions on ability to get the medication. Affordability is impacted by the number of times per year they need to see a GP for a prescription, number of times they need to visit the pharmacy to get medication, and the cost of the medication itself (bigger packs may be cheaper than multiple smaller packs).

The larger pack sizes of opioid medicines will still have a place in pain management for some patients.

[I have] chronic pain affecting mobility. Fatigue that wipes me out for days, often unable to do more than get out of bed.

The Women's Centre for Health Matters highlighted this in their recent research<sup>10</sup>. Some women's experience of episodic pain and debilitating conditions is that

... the episode may last for a month or more. Therefore, it is necessary that some women have access to a larger supply of medications to deal with the nature of these severe conditions.

We also had some consumer feedback that sometimes a prescription of only three days may be a little too short, even for acute pain. We propose that smaller pack sizes for opioid medications need to be based on the clinical evidence available for the types of conditions/pain for which they are likely to be prescribed. Ultimately it is important for prescribers to have plenty of flexibility in responding to the varying

<sup>&</sup>lt;sup>9</sup> A Hutchison, 'I don't have the spoons for that...' The views and experiences of younger ACT women (aged 18 to 50 years) about accessing supports and services for chronic disease, Women's Centre for Health Matters, 2018

<sup>&</sup>lt;sup>10</sup> Ibid.

needs of individual patients, recognising that some cases will be more complex than others.

#### **Challenges**

The challenges for implementing this option include:

- changing prescriber behaviour to ensure that the smaller pack sizes were prescribed in all cases other than those approved for the larger pack sizes
- ensuring good communication between
  - o consumers with acute pain and health professionals, and
  - between health professionals (e.g. surgeon communicating back to the GP) about the need to reduce the dose, then cease the opioid medication, and follow-up where appropriate
- PBS restrictions for subsidy might need to differentiate between pack sizes in accordance with therapeutic guidelines.

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

  The TGA will review indications for the S8 opioids and align them to current clinical guidelines for appropriate prescription of these products.
- HCCA supports a review of indications for S8 opioids to ensure they are aligned with current evidence-based clinical practice.

It is important that evidence-based clinical practice guide the prescribing of appropriate opioid treatment for individuals. We also would like to ensure the good use of public subsidy through the PBS. A consumer commented that:

PBS concessional patients would likely pay the same amount (currently \$6.40) for both the current pack size of 20 tablets, or a 'post-op' pack of 6 tablets, given the PBS pricing algorithm. This would likely introduce perverse incentives for patients to request the larger pack size, in circumstances where the smaller pack size was more appropriate.

The cost of prescriptions for concessional patients will need to be considered in any future changes.

# Option 3 Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing Review the place of the higher dose S8 opioid products in the management of chronic cancer and non-cancer pain and whether certain high dose products should continue to be registered. We would consider if specific controls, such as approval to prescribe through states and territories or the PBS should be introduced.

• HCCA does not support Option 3. We are concerned that it would reduce consumer access to medicines they need.

HCCA has concerns about the impact of this regulatory option on consumer **access** to medicines they need. A consumer commented:

Restricting who can prescribe high dose opioids is likely to impact on consumers' access to those medicines. If prescribing high dose opioids was restricted to specialists, consumers living in rural and remote areas [or even outer metropolitan localities] may face difficulties in attending specialist appointments given:

- their condition (such as terminal illnesses);
- their access to transport; and/or
- the availability of appropriate specialists in their locality.

#### Another consumer commented that:

Making it more difficult for chronic pain patients to obtain pain medication will drive the access to medication underground which is likely to have a worse outcome on society.

#### Pain Support ACT also commented that:

Limiting prescribing in this way could lead to further significant demand on specialists / approved prescribers with high costs to consumers and further increases in wait periods for people in pain.

Access to doctors, particularly specialists and pain management clinics, is a significant problem in the ACT. At HCCA we frequently hear of patients who travel considerable distance interstate to access the health care professionals they need.

We suggest that using a real-time prescription monitoring system nation-wide would mitigate many of the risks that this regulatory option seeks to address through limiting prescribing and consumer access.

#### Real-time prescription monitoring and fentanyl

A case may be made for separating out the medication fentanyl in this discussion, because it is such an exceptionally potent pain-killer. It is potentially a very high-risk medication, but one that definitely has a role to play in treatment for certain patients. For example, HCCA heard a consumer story about fentanyl being prescribed for surgery and post-operative pain for a chronic pain patient who did not easily tolerate morphine. We suggest that fentanyl is only prescribed by highly-skilled prescribers. A nation-wide real-time prescription monitoring system would add value here.

# Option 4 Strengthening Risk Management Plans for opioid products Review current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks

HCCA has no specific comment to make on this option, which is similar to option two in that it seeks to address changes in the regulatory requirements since some opioids were first registered in Australia.

## Option 5 Review of label warning and revision to the Consumer Medicines Information

Under this option, warnings could be placed on the packaging of opioid products identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of chronic non-cancer pain, noting that the complexity of appropriate management of chronic non-cancer pain needs to be recognised. The CMI would also be reviewed to provide greater emphasis on risks of dependence, especially those associated with high doses.

• HCCA is broadly in favour of Option 5, as additional packaging warnings may support informed choice about medication use. However, HCCA recognises that some additional warnings (depending on their wording) may conflict with advice and could appear to consumers to undermine the judgement of their prescribing clinicians. It is important that prescribing doctors have ample opportunity and the skills to discuss the benefits and risks of medications with consumers, in the context of shared decision-making about treatment.

Feedback from consumers on this option was mixed, but the common theme was that good communication between patients and health professionals is critical. Simply using warnings on medications and/or making changes to the CMI is insufficient – the use of opioids needs to be a discussion in the context of shared decision making.

In our consultation with consumers, there was a strong feeling that written information provided to patients/carers, like CMI or information on medicine labels, can strengthen verbal advice, if the verbal advice has been understood. Pain Support ACT told us:

Most chronic pain patients encountered by Pain Support [ACT] are interested in using their medications responsibly and in ways which will give them most value in addressing their pain and their capacity to function. Such warnings are likely to remind them to manage their medications closely and carefully and seek assistance (e.g. from a pharmacist, if they have any worries or may have made an error).

Other consumers felt that a greater emphasis needs to be placed on communicating to patients the place of opioid medicines in treating pain, the risks of addiction and where appropriate, how to reduce the dose with a view to ceasing the medication.

The Women's Centre for Health Matters (WCHM) was supportive of additional labelling and warnings:

Labels and warnings about the risk of dependence and overuse would be a positive addition to packaging. The label should be clear and non-stigmatising with encouragement to look for more information on pain management. We suggest a helpline service where women can talk about risk of dependence and opioid overuse. Using a service that already active such as Health Direct may be viable option as long as workers get additional training.

WCHM felt that increased information about the risks posed by strong opioids would help consumers to make an informed choice about whether or not to use these medications. However, there was also concern that placing information on medicine labels to say that the medicine lacks efficacy in chronic non-cancer pain may, for the consumer, undermine the judgement of their prescribing clinician.

Consumers rightly expect to develop a strong and lengthy clinical relationship with their treating practitioner when managing chronic non-cancer pain. There is the potential that consumers could receive mixed messages if the labelling shadows doubt on the clinical competence of their practitioner.

There are some consumers who avoid taking pain medication at any cost – who feel that taking even relatively low-level pain medication presents a great risk. Without good communication, label warnings or information contained in a CMI may unnecessarily raise fear to the point that a patient may not take the pain medication, even when it would provide significant benefit. For example, post-operatively, pain medication might help to increase mobility to speed and enhance recovery. Appropriate use of medication can help to counter pain before it starts or returns in full-force when managing pain, or during the post-operative period. This needs to be part of the conversation between the patient and health professional so that the balance of the risks and benefits can be fully understood, and where medication does provide an advantage for the individual, they can see the potential gains such as improved functionality or sleep.

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

Provide priority review to new chemical entities that are viable alternatives to opioids for pain relief and also expedite the review of smaller pack sizes and/or abuse-deterrent formulations and products that can be used to negate the effect of opioids.

HCCA has no specific comment with regards to this option. It is likely that consumers and health professionals would welcome any new viable alternatives to opioids for pain relief.

Consumers have reported to us that since the rescheduling of codeine in February 2018, some pharmacies have been promoting non-prescription combination products (such as paracetamol and ibuprofen together in one tablet) as an alternative to prescription opioids for pain. We feel it is important to emphasise that the evidence for these products is short-term use only, even though they are available in large quantities – consumers need to be made aware of these limitations when purchasing, know what to do if pain persists, and be provided with supporting information, such as CMI<sup>11</sup>.

<sup>&</sup>lt;sup>11</sup> NPS MedicineWise: Paracetamol/ibuprofen combinations for acute pain, 9 October 2017 <a href="https://www.nps.org.au/medical-info/clinical-topics/news/paracetamol-ibuprofen-combinations-for-acute-pain#information-for-patients">https://www.nps.org.au/medical-info/clinical-topics/news/paracetamol-ibuprofen-combinations-for-acute-pain#information-for-patients</a> [accessed 7/3/2018]

#### **Option 7**

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

Powers under medicines scheduling could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels.

The previous comments for Option 3 are relevant here, in the context of potential restrictions on who can prescribe certain medicines having an adverse effect on consumers' access to those medicines.

Many consumers experience significant barriers to accessing specialist clinicians and specialist pain management services. As an example, the Women's Centre for Health Matters advised HCCA that participants in their recent research<sup>12</sup> reported:

affordability, availability of specialists, time it takes to access services, wait times and not being believed as barriers affecting their ability to access specialists.

These commonly-experienced barriers have led HCCA to form the view that high dose opioids should not be restricted to specialist prescription only. However, authority prescription from a GP may be acceptable.

<sup>&</sup>lt;sup>12</sup> A Hutchison, 'I don't have the spoons for that...' The views and experiences of younger ACT women (aged 18 to 50 years) about accessing supports and services for chronic disease, Women's Centre for Health Matters, 2018

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

Existing clinical guidelines for the management of acute and chronic pain provide advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain. While these are available there may be limited health practitioner awareness and uptake.

 HCCA is supportive of Option 8. There is clearly a place for opioid therapy for some patients in the 'toolbox' of pain management, but the key principle should be to increase the broad knowledge and understanding of health professionals, along with consumers, in treating pain with the full range of therapeutic options available (both pharmacological and non-pharmacological)

HCCA understands that the development, promulgation and management of clinical guidelines are not controlled by the TGA. However, we do support a focus on awareness of health professionals about the range of pain management options available. As Pain Support ACT told us:

[This would] bring the pain crisis for members of the community, not just the opioid crisis, under better control... Opioids do have their uses in the management of chronic pain and consumers who suffer continuous, significant pain really want to see as many options as possible used which might help them.

The real opportunities we see are in encouraging, training and supporting health professionals to adopt a "tool box" approach (i.e.. making use of the wider range of useful options, including the most effective use of opioids and other non-opioid medications, as well as all the gamut of multidisciplinary care, rehabilitation strategies, pain and self-management education, which are also evidence-based in their contribution to reducing pain. Consumers generally want their pain resolved as quickly as possible, but it is up to health professionals to work with patients in a process of shared decision making to consider the various drug and non-drug options, including advice on costs, risks and timeframes, to decide what will work best for them. Consumers may then also need advice and assistance about how to access services beyond medication. Pain Support ACT has long been a great support to consumers in this area.

HCCA is strongly supportive of the benefits of such an approach. Unfortunately, clinicians are not all equally skilled in applying a shared decision-making approach to the management of their patient's chronic or acute pain. The Women's Centre for Health Matters' recent research with young ACT women (18-50) found that many

experienced a dismissive attitude from health professionals when they explained their experience of pain<sup>13</sup>. On participant summarised her experience of:

Discrimination, assumptions about my illness that were untrue, lots of 'we can't help you', sexist and derogatory comments from male health practitioners, spoken to like a child, told i wasn't 'trying' hard enough, lack of clear answers, no follow up.

It is essential that health professionals take consumers' complaints of pain seriously, as a precursor to engaging both medical and non-medical approaches to pain management in consultation with the consumer and with respect to the consumers' priorities and preferences for treatment. HCCA recognises that alternative treatments may be higher cost to consumers because they are not publicly subsided, and urges that all efforts be made by Australian Governments and health services to ensure that alternative treatments are affordable and accessible to health care consumers.

In the ACT there is a significant wait time for specialist pain management options, such as the Pain Management Unit at The Canberra Hospital. It is very important that sufficient services are provided to meet demand and need from consumers, at times, places and costs that are appropriate for the people who require them.

#### **Concluding remarks**

HCCA looks forward to seeing how our feedback and comments shape improvements in addressing pain management with consumers and in addressing the use and misuse of opioid medications in Australia. Please do not hesitate to contact us if you wish to discuss our submission further. HCCA would be happy to clarify any aspect of our response.

<sup>&</sup>lt;sup>13</sup> A Hutchison, 'I don't have the spoons for that...' The views and experiences of younger ACT women (aged 18 to 50 years) about accessing supports and services for chronic disease, Women's Centre for Health Matters, 2018

#### References

- Roughead, L., Semple, S., Rosen Feld, E. Literature Review: Medication Safety in Australia, Australian Commission of Safety and Quality in Health Care, August 2013. <a href="https://safetyandquality.gov.au/wp-content/uploads/2014/02/Literature-Review-Medication-Safety-in-Australia-2013.pdf">https://safetyandquality.gov.au/wp-content/uploads/2014/02/Literature-Review-Medication-Safety-in-Australia-2013.pdf</a> [accessed 20/02/2018]
- National Medicines Policy, Australian Government Department of Health and Ageing, 2000.
   <a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029">http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029</a> EEAC8CA257BF0001BAF3F/\$File/NMP2000.pdf [accessed 20/02/2018]
- 3. Shared Decision Making, Australian Commission on Safety and Quality in Health Care <a href="https://www.safetyandquality.gov.au/our-work/shared-decision-making/">https://www.safetyandquality.gov.au/our-work/shared-decision-making/</a> [accessed 27/02/2018]
- Hunt, G. (Media Release) National approach to prescription drug misuse, 28
   July 2017.
   <a href="http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt071.htm">http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt071.htm</a> [accessed 26/02/2018]
- 5. Pain Australia. *Access to Pain Management, A Fundamental Human Right*. Available at: <a href="http://www.painaustralia.org.au/improving-policy/human-right">http://www.painaustralia.org.au/improving-policy/human-right</a>. [accessed 1/3/2018].
- Medicines, Poisons and Therapeutic Goods (Category Approval)
   Determination 2018 (No 1) <a href="http://www.legislation.act.gov.au/ni/2018-77/current/pdf/2018-77.pdf">http://www.legislation.act.gov.au/ni/2018-77/current/pdf/2018-77.pdf</a> [accessed 9/03/2018]
- 7. Hutchison, A. 'I don't have the spoons for that...' The views and experiences of younger ACT women (aged 18 to 50 years) about accessing supports and services for chronic disease, Women's Centre for Health Matters, 2018.
- 8. NPS MedicineWise: Paracetamol/ibuprofen combinations for acute pain, 9
  October 2017 <a href="https://www.nps.org.au/medical-info/clinical-topics/news/paracetamol-ibuprofen-combinations-for-acute-pain#information-for-patients">https://www.nps.org.au/medical-info/clinical-topics/news/paracetamol-ibuprofen-combinations-for-acute-pain#information-for-patients</a> [accessed 7/3/2018]