Australian Pain Management Association Inc. (APMA) response to the

Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory discussion paper issued by theTherapeutic Goods Administration

2 March 2018

Who we are

The Australian Pain Management Association Inc. (APMA) is the national consumer health charity which advocates on behalf of the more than 3.2 million Australians from all walks of life estimated to be suffering from chronic (persistent) pain and supports individuals with chronic pain conditions, and their families across Australia.

The organization was established in 2009 in response to the need for evidence-based information and services for people living with chronic pain, and to provide a voice and community support. It has hundreds of members in all States and Territories of Australia, in metropolitan, regional and remote locations, with a wide variety of pain conditions and associated co-morbidities such as depression and obesity.

APMA works with governments, health administrators, clinician, research and community organisations. APMA provides advice, advocacy and representations to governments, clinicians and health departments and administrators on behalf of people living with pain (see http://www.painmanagement.org.au/about_us/what-we-do-main-menu/assistance/advocacy.html).

Setting the scene – The extent of chronic pain across Australia

Chronic pain is a major health challenge for Australia. The management of pain in Australia remains shockingly inadequate, despite the efforts of health practitioners, consumer organizations and in recent years, State health authorities. One in five Australians will suffer persistent pain in their lifetime yet up to 80% living with this debilitating condition are missing out on treatment that could improve their health and quality of life. Access Economics in 2007 estimated that persistent pain costs the Australian economy $34 billion per annum, is Australia's third most costly health problem and as the population ages the numbers and costs are only increasing[1].

In Australia, approximately 19% of the population are currently affected by moderate to severe chronic pain. 33% of these sufferers had pain with high disability that was moderately to severely limiting. Overall, it has a considerable impact on quality of life, resulting in significant suffering and disability[2]. While in many cases it is accepted that a cure is unlikely, the impact on quality of life, mood and function can be greatly reduced by early and best practice measures.

As can be seen in Table 1 below, low back pain is ranked as the number one health burden in every age category apart from the 5-14 age group (where it is ranked number three) for disability-adjusted

[1] Access Economics Pty Ltd *The High Price of Pain: The economic impact of persistent pain in Australia* MBF Foundation November 2007

[2] Australian Institute of Health and Welfare, Patient-based substudies from BEACH: abstracts and research tools 1999-2006, Prevalence and Management of Chronic Pain, http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=6442456168

life years for burden of disease in Australasia[3]. It carries the highest ranking for "All ages". Neck pain also carries a high burden of disease, ranked number four in the combined 15-64 age category and number three across all age groups. Low back pain may be either acute or chronic but it is the chronic low back pain and neck pain which will increase the burden of disease, as the longer the conditions persist if not well managed. Low back pain is not a national health priority despite having a higher burden of disease than asthma, diabetes, Alzheimer's disease, ischemic heart disease, major depressive disorders and hearing loss.

Chronic pain not only has an impact on affected individuals and their families, it also has substantial economic costs. For example, health related expenditure on back pain alone was estimated to cost $1.2 billion (1.8% of disease related spending) in 2008-09[4]. The vast majority of patients with back problems will receive no treatment other than that available in the primary care sector. It is critically important that general practitioners (GPs) and other healthcare professionals have the best possible resources and support to manage their patients properly and have different modes of access to appropriate specialist services when required. The number of patients requiring GP services has grown from 2.7 of every 100 GP-patient visits in 2003–04 to 2.9 in 2012–13[5]. Only a proportion of patients who require access to specialist secondary and tertiary care pain services will manage to obtain such services. From 2003–04 to 2012–13, the hospitalisation rate (aged 45+) for back problems increased from 762 per 100,000 to 882 per 100,000.[6]

[3] Disability-adjusted life years is a composite of life lost due to premature death from the disease and years lived with illness or disability from the disease. The greater the disability-adjusted life years (DALYs), the greater the burden of disease.

[4] http://www.aihw.gov.au/back-problems/expenditure/

[5] http://www.aihw.gov.au/back-problems/treatment-by-gps/

[6] http://www.aihw.gov.au/back-problems/treatment-by-hospitals/

	Ages 5–14	Ages 15–49	Ages 50–69	Ages 70 +	All ages
1	Asthma	Low back pain	Low back pain	Low back pain	Low back pain
2	Major depressiv e disorder	Major depressive disorder	Other musculoskele tal	Alzheimer's disease	Major depressive disorder
3	Low back pain	Drug use disorders	Falls	Falls	Neck pain
4	Conduct disorder	Neck pain	Neck pain	COPD	Other musculoskele tal
5	Anxiety disorders	Anxiety disorders	Major depressive disorder	Other musculoskele tal	Falls
6	Iron-deficiency anemia	Migraine	COPD	Diabetes	Anxiety disorders
7	Neck pain	Other musculoskele tal	Diabetes	Other hearing loss	Asthma
8	Eczema	Asthma	Anxiety disorders	Ischemic heart disease	Migraine
9	Migraine	Alcohol use disorder	Osteo-arthritis	Neck pain	Drug use disorders
10	Thalasse mia	Falls	Migraine	Major depressive disorder	COPD

Table 1: Burden of disease, Australasia (nb. Includes Australia and New Zealand)[7]

A wide range of both pharmacological and non-pharmacological management strategies are necessary for chronic pain. In 2008-09 13.0% of all prescription pharmaceuticals ($153 million) was spent on low back pain, not including privately purchased over-the-counter medication. The challenge is to understand the extensive published evidence for opioid treatments and to determine when and where to use them for the best long term patient outcomes.

Introductory remarks

There are a range of different categories of pain, including acute, chronic, neuropathic and cancer-related pain. Living with and managing persistent pain requires reliable and up-to-date medical

[7]Information derived from AIHW http://www.aihw.gov.au/asthma/health-burden/

treatment (including allied health and pharmaceutical assistance). It also needs self-management capability, utilising lifestyle information, activity and support. A combination of these measures can restore function and quality of life to individuals whose main disability is pain.

The Australian Pain Management Association is disappointed that the first sentence of the consultation paper, *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response*, begins with the 'misuse of opioids' rather than the intentional and mostly well managed use of opioid medications for pain management. We see this as problematic in that it sets a theme of the document that inappropriate use and addiction are more important and over-ride the need for pain management. The consultation paper is concentrating on the minority of prescribers and patients who are problematic rather than the vast majority of the "almost 3 million people…prescribed at least one opioid."

The APMA concurs that there is a crisis in the USA with regard to deaths from strong opioids but rejects suggestions that there is such a 'crisis' in Australia. The public health system in Australia is robust and universal, markedly different from that in the USA. As well, some public patients have access to publicly funded pain management services which provide a multidisciplinary response to chronic pain with a greater emphasis on non-pharmacological modalities.

There has been an increase in strong opioid prescribing since 2000. It must be noted that Australia has an ageing population and the likelihood of developing painful health condition increases. APMA does not want to see a situation where patients cannot receive strong opioid medication when patients have severe to very severe pain and strong opioids are deemed clinically appropriate by their treating doctor. Chronic disease is prevalent in Australia. In 2014-2015 at least 50% of Australians had at least one chronic condition rising to 87% in the over 65 age group. APMA would not like Australia to go back to the 'dark days' when opioids were only given for extreme pain at the very end-of-life.[8]

National Pharmaceutical Drug Misuse Framework for Action (2012-2015)

APMA recognizes that a scaled up regulatory approach could help doctors improve individualised medicine when prescribing strong opioids. APMA has been a strong advocate for the implementation of the *National Pharmaceutical Drug Misuse Framework for Action 2012 – 2015*. We believe it is likely to reduce the associated harms while not discriminating against chronic pain patients and will ensure opioid availability on clinical grounds. Alas, it is yet to be applied across the Australian health system.

APMA agrees that the regulatory measures identified in the Framework would support quality prescribing and benefit patients. APMA supports the implementation of all the six items:

- *Real time prescription monitoring*
- *Medication labelling reforms*
- *access to tamper-resistant medications*

[8] Australian Institute of Health and Welfare 2016. Australia's health 2016. Australia's health series no. 15. Cat. no. AUS 199. Canberra: AIHW.

- *exploring opportunities to improve access to non-opioid adjuvant medications for pain conditions*
- *where possible, enhancing the range of medication pack sizes and/or dispensing options for PBS medications*

Can some of the problems with opioids potentially be addressed – at least in part – through regulatory measures?

APMA believes that the following points should be taken into account when considering the problems of opioids.

Firstly, patients (and some health professionals) put an over-emphasis on medication strategies to relieve pain. The belief that opioids will take all the chronic pain away forever is not a realistic one even for strong opioids, over the long term. The APMA Pain Link helpline and pain support groups are in daily contact with patients wanting access to much improved medication and are dissatisfied with the pain control of current medicines.

Secondly, Australia has a number of expert hospital based pain management services in mostly major city based hospitals. This enables a small percentage of patients with chronic pain to access these services. Most patients with chronic pain though, do not get this opportunity. There are very few community based pain programs and the ones that exist in Melbourne and surrounds are highly regarded by patients. Unless patients have access to quality individualised pain management delivered by a range of allied health, nursing and medical staff, they will not know how and why multidisciplinary pain management works. That is, they will be stuck in the acute pain model where many will be resting up, depending on analgesics to reduce their pain by a high margin and waiting for their chronic condition to heal and their pain to resolve. Under this regime patients deteriorate physically, emotionally and socially developing a broad spectrum of problems because there are not the dedicated health services that exist for chronic pain in Australia.

Thirdly, patients with chronic pain face stigma about their condition as well as their use of medications. There are inadequate community and social support, especially compared with other chronic conditions such as arthritis, asthma and diabetes. These well established chronic conditions have well resourced patient support services which are able to perform health educational and social support roles. These functions are underpinned by robust research underpinning the patient benefits from health education, support groups and phone and internet services. Unfortunately APMA, the only organization delivering services such as a helpline and pain support groups for people who live with severe persistent pain can only deliver these services using volunteers who have great difficulty keeping up with the level of patient demand.

As the discussion paper notes, there is a need to improve patient education across Australia.

It is heartening to note that the federal government has approved funding for the Electronic Recording and Reporting of Controlled Drugs (ERRCD), one of the Framework's recommendations. There is now a clear objective for the state and territory health systems to employ which will go a long way to limiting unsanctioned use of opioid medications.

Option 1: Consider the pack sizes for Schedule 8 opioids

APMA believes that packet size for strong opioids could be considered for hospital discharge as part of acute pain and the minimum packet size be for one week, as part of a changed regulatory response.

However, APMA contends it will create undue hardship for patients if there is a need to go back to see a doctor to have the script revised in under four weeks for people with non-acute pain.

Furthermore, APMA believes that changes to the PBS should not be made and that the status quo remain. General practitioners prescribing strong opioids for their patients for "chronic severe disabling pain which is unresponsive to non-opioid analgesics" should be able to prescribe these medicines for various chronic conditions creating severe pain. As well, these GPS do not need to have another doctor review their practice for patients with chronic pain.

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

Whilst there may be some justification for continuing professional education around the opioids and pharmacology and patient suitability, APMA does not believe that strong opioids should not be available for the more than 500 conditions that result in chronic pain.[9]

Research suggests that for patients to be able to participate in physical and cognitive therapies pain needs to be reduced to a tolerable level so that the patient can take an active part in the rehabilitation. APMA does not want the TGA's regulatory approach to take away the doctor's ability to use clinical judgement to include prescribing strong opioids.

There is high patient variability in responding to pain treatments whether it be opioids, antiepileptics, antidepressants or medical procedures such as epidurals. There are only a minority of patients who will achieve a fifty percent pain reduction from any one modality.

Women have a higher incidence of chronic pain than men and it is already acknowledged that they receive less treatment than their male counterparts. APMA believes that the blunt regulatory options proposed means that women will again be discriminated against and labelled as 'hysterical' for saying they are in pain, not believed and, in the extreme, not being taken seriously. This will mean that women with extreme pain from pelvic mesh implants, for example, may not be prescribed opioid analgesia even when strong analgesic medication is warranted.

Often chronic pain patients who do not have adequate pain control can end up with persistent fatigue. Sleep deprivation commonly causes disability and suffering when left untreated by clinicians. Additionally, fatigue can lessen patients' ability to participate in rehabilitation therapy aimed at increasing physical activity, such as graded movement, thus lowering its effectiveness.[10]

[9] National Pain Strategy, Developed by the Pain Summit Initiative, 2010, P.14

[10] Tired of pain? Toward a better understanding of fatigue in chronic pain, Stefaan Van Dammea, Susanne Becker, Dimitri Van der Linden, PAIN January 2018·Volume 159·Number 1

Pain interrupts patients' ability to pay attention to tasks at hand. This intrusion can result in patients paying pain all their attention and away from other activities that require their concentration. Patients who are able to have pain at a tolerable level are more able to focus on their activities of daily life.[11]

Empirical evidence has shown that patients with chronic pain not recceiving adequate pain control, the expectation of ongoing pain can lead to avoidance of physical or cognitive therapy which in turn can undermine patients acquiring pain coping skills. Studies influencing pain expectations have found that patients that expect future pain are likely to have higher future pain experience and avoid activity and disability. Expectations of pain seem to be a significant factor for future pain experience and functional performance.[12]

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

APMA does not support the proposition that only specialists should be able to prescribe the stronger morphine or morphine like drugs. This will be extremely restrictive for physicians and problematic for patients who live regionally or who do not have the capacity to pay private specialists. It is very difficult for many public patients to get appointments to see hospital based pain specialists at all.

However, APMA also has increasing concerns around the drug fentanyl and agree that it should be restricted in the indications it can be prescribed for.

Naloxone Research

APMA is on the advisory board for the research into understanding the impediments to uptake and diffusion of take-home naloxone in Australia, funded by the Australian Research Council. Currently, naloxone is not prescribed alongside a prescription for opioids for patients with chronic pain. APMA agrees that the "risk of overdose with these products" is high and that naloxone could be prescribed concurrently. Pharmacists could play a role in educating patients and carers on the use of naloxone.

Option 4: Strengthening Risk Management Plans for opioid products

APMA agrees there is a role for the National Prescribing service as well as medical colleges to play in continuing medical education about opioid prescribing.

[11] Cognitive load selectively influences the interruptive effect of pain on attention, David J. Moor, Christopher Eccleston, Edmund Keogh, October 2017·Volume 158·Number 10

[12] Predictors and social consequences of daily pain expectancy among adults with chronic pain,Chung Jung Muna, Kirti Thummala, Mary C. Davis, Paul Karoly, Howard Tennen,, Alex J. Zautra, PAIN ·158 (2017) 1224–1233

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

APMA agrees that warnings on labels could be strengthened. The risk of overdose, especially in combination with alcohol and other drugs needs to be made very clear.

However, APMA does not believe it is practicable to include "… the complexity of appropriate pain management of chronic non-cancer pain needs to be recognized."

APMA is concerned that the TGA is making general claims about treating "chronic non-cancer pain" and emphasises that there are an extremely wide range of health diseases and conditions falling under this broad umbrella term. It is inconsistent with individualised and person-centred medicine not to take into account the wide range and seriousness of the conditions that lead to moderate to severe chronic pain

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

APMA is supportive of Option 6. People living in chronic pain have a highly varied individual response to pain relief medications. As such APMA believes that patients require the most effective relief as early as possible. Any incentive that can be provided to industry is welcome. Anecdotally, Australians with chronic pain become desperate and vulnerable to products that have no efficacy but powerful marketing claims. People with pain often spend large sums on unproven treatments that are unlikely to benefit their pain control. Patients need a range of analgesics that are less harmful than strong opioids but at least as effective.

The TGA could further consider clamping down on inflated or misleading claims by companies manufacturing pain relief eg homeopathic treatments.

The TGA has registered some GPs to be able to prescribe medicinal cannabis. The federal and state regulations process should have the same rigour as for Schedule 8 drugs, but should not be made more onerous. Health jurisdictions in countries such as Canada, Netherlands and Israel all have much simpler procedures and patients are able to be treated with medicinal cannabis by their doctors.

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

The APMA supports further education for all prescribers of strong opioids. APMA believes that doctors' education befits them to be able to prescribe strong opioids. Consequently, APMA does not support limiting *prescribing of S8 opioids to certain medical practitioners (such as palliative care physicians for high-dose opioids in patients with cancer pain and specialist pain medicine physicians for high-dose opioids in patients with chronic non-cancer pain).* APMA believes this will have significant repercussions for large numbers of patients, including: limited access – there are simply

nowhere near enough pain medicine specialists who could treat the more than 3.2 million patients with chronic pain; not having a local doctor who knows the patient best prescribing strong pain medication and the onerous cost of attending specialist appointments.

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

APMA believes that there are extremely limited alternatives to opioids, especially non-pharmacological, for prescribers. The best practice pain management is multidisciplinary pain management, ideally located at the community level. However, there are relatively few of these in the community health arena. If these were far more available then patients and prescribers would have best practice, multi modal pain management.

Currently, pain management centres in major hospitals have long and growing waiting lists which deters prescribers and patients from using them.

Chronic disease plans allow patients to attend five allied health appointments each year. However, patients with chronic pain often need a range of health care practitioners delivering physical and cognitive therapies which are coordinated by the patient's GP. This is rarely common practice at present.

Conclusion

APMA endorses the following regulatory responses which can be implemented to improve prescribing of strong opioids. These include:

- Real time prescription monitoring
- Medication labelling reforms
- Minimum packet size not less than one week
- Restrictions for fentanyl prescribing
- Concurrent prescribing of naloxone alongside strong opioids
- Warnings on labels could be strengthened
- TGA could clamp down on inflated or misleading pain management claims

Further regulation won't work on its own unless there are other pain management options for patients. Further regulation is the arm the government can use to limit supply of strong opioids. APMA recommends that there be far more community based pain clinics for patients to access to be treated for chronic pain as well as recognized and funded community support such as pain support groups and a national telephone helpline. Medicinal cannabis could also be a useful analgesic for some patients and the TGA is urged to collaborate with State health departments so that doctors are able to be registered and able to prescribe without undue regulation. That is, prescribing medicinal cannabis should not be any more onerous than prescribing strong opioids. Access to strong opioids to relieve severe pain must still be the primary focus when considering further regulation of strong opioids.