

**pain**australia

# Inquiry into approval processes for new drugs and novel medical technologies in Australia

*October 2020*



## Inquiry into approval processes for new drugs and novel medical technologies in Australia

Painaustralia is pleased to provide input to inform the House of Representatives Standing Committee on Health, Aged Care and Sport as they inquire into the approval processes for new drugs and novel medical technologies in Australia (the Inquiry), with a particular focus on those for the treatment of rare diseases and conditions where there is high and unmet clinical need.

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Members include pain and other specialists, health practitioners, health groups, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue.

Access to appropriate and safe medicines is a key part of any modern health system. Consumers in Australia place a high value on the role the Pharmaceutical Benefits Scheme (PBS) plays in providing timely, reliable and affordable access to necessary medicines.

One in five Australians aged 45 and over are living with persistent, ongoing pain, which is often disabling and stressful<sup>1</sup>. Chronic pain affects the quality of life of over 3.37 million individuals and carries a significant economic burden in lost productivity and health costs. Experts have posited that the COVID-19 pandemic may significantly increase the number of people experiencing chronic pain, as many survivors experience post-viral conditions; and that the mental and physical health impacts of the virus may exacerbate pain amongst existing sufferers.<sup>2</sup>

Addressing pain is in the interests of all Australians. Yet people living with pain are often unable to access the right assessment and care, and many fall between the gaps of our healthcare, mental health and disability systems. Medication has played an increasing role in managing pain, and over-reliance on opioids is an unfortunate symptom of a system that is not working as it should for many people with chronic pain.

Governments, policy-makers, health practitioners and care givers must also recognise that chronic pain and opioid use and other medication misuses and disorders are complex conditions, and each can cause significant disability, social exclusion and a diminished financial situation. This not only relates to the cost of prescriptions, but the low availability and access to multidisciplinary pain services and alternatives that enable patients to find better ways to manage pain, increase activity, improve health and wellbeing and make the best use of pain medications.<sup>3</sup> At least 80 per cent of people living with chronic pain are missing out on treatment that could improve their health and quality of life.<sup>4</sup>

Without affordable access to best practice treatment and alternatives, we must recognise that millions of people will continue to rely on medications to manage their pain. The use and dependency on pharmacological pathways is widespread, and in some instances the only option for consumers. We must carefully consider our regulatory environment and understand the impact access to pain management medications, both current and novel, can have on the quality of life for millions of consumers.

## BACKGROUND

### The growing prevalence and cost of pain

Painaustralia's report, *The Cost of Pain in Australia* by Deloitte Access Economics, provides the most comprehensive analysis of the financial impact of chronic pain in Australia. It shows that chronic pain affects more than 3.4 million Australians. Chronic pain, also called persistent pain, is pain that continues for more than three months after surgery, an injury, as a result of disease, or from another cause.

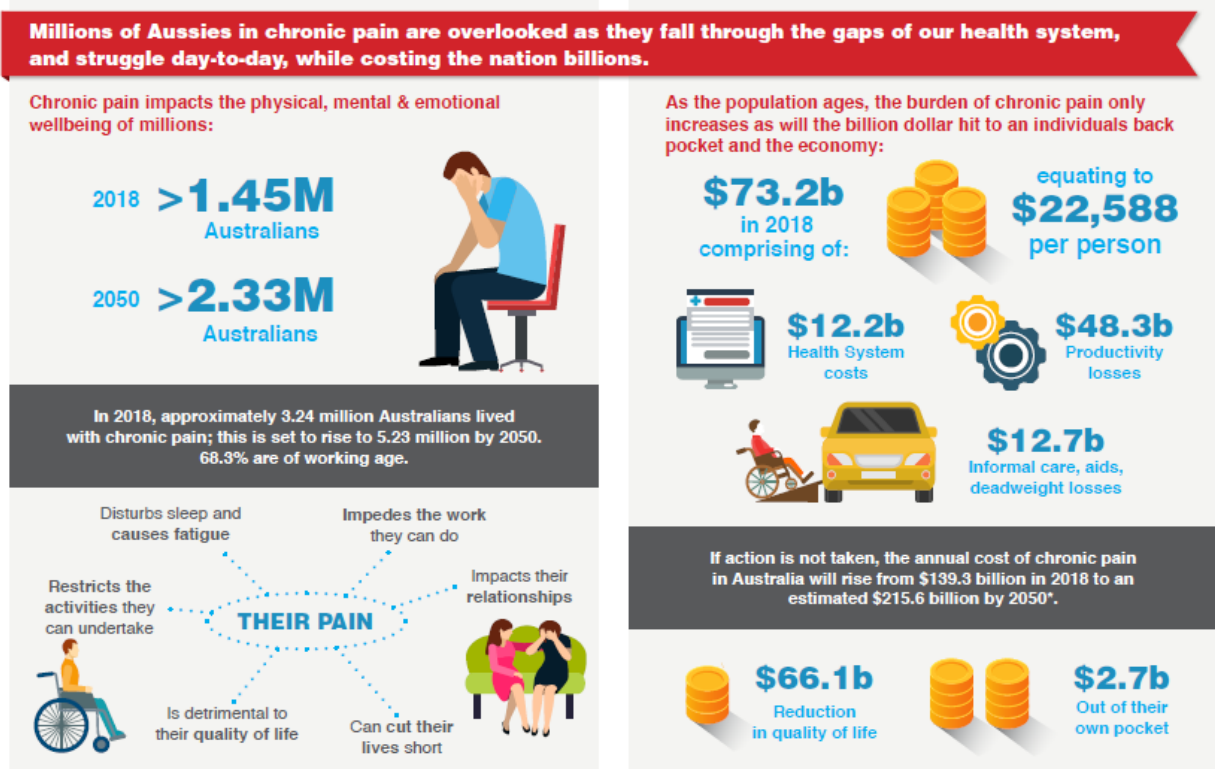
For those who experience chronic pain, the pain can be debilitating and have an adverse effect on work, sleep, and relationships. Individuals with chronic pain may also commonly experience comorbidities such as depression, sleep disturbance and fatigue.

These comorbidities often contribute to worse health, societal and financial outcomes – for example, major depression in people with chronic pain is associated with reduced functioning, poorer treatment response, and increased health care costs. Nearly 1.45 million people in pain also live with depression and anxiety. Painaustralia's report finds that the reported comorbidity for chronic pain and depression or anxiety is estimated at 44.6 per cent of patients, which is within the range of estimated values from international literature.<sup>5</sup>

The consequences of these gaps are immense. The price paid by people with chronic pain is continued physical and psychological ill health, social exclusion and financial disadvantage. Opioids continue to be over-prescribed for pain, with unacceptable consequences including dependency and opioid-related deaths.

Society pays the price too. The total financial costs associated with chronic pain were estimated to be \$73.2 billion in 2018, which equates to \$22,588 per person with chronic pain.<sup>6</sup>

More than 68 per cent of people living with chronic pain are of working age. Without action, the prevalence of chronic pain will increase to 5.23 million Australians (16.9 per cent) by 2050. In 2018, the staggering cost of chronic pain to taxpayers (including quality of life) was \$139 billion. This was on top of the fact that last year alone, Australians paid \$2.7 billion in out of pocket expenses to manage their pain, with costs to the health system in excess of \$12 billion.



## The impact of inaction

Despite the burgeoning cost and impact of pain, our current clinical pathways are failing consumers. An epidemic of pain in Australia has seen problematic increases in the level of harm and deaths due to opioid misuse. With over three million people prescribed 15.4 million opioid scripts in 2016–17 it is unsurprising that opioids now account for 62 per cent of drug-induced deaths, with pharmaceutical opioids now more likely than heroin to be involved in opioid deaths and hospitalisations.<sup>7</sup> In 2016–17 there were 5,112 emergency department presentations and 9,636 hospitalisations due to opioid poisoning, with three deaths per day attributed to opioid harm, higher than the road toll.<sup>8</sup>

Currently, the MBS does not support a best-practice treatment model, leading to unnecessary use of hospital-based services and more significantly, an over-reliance on medication including opioids, which is associated with significant harm. Nearly 70 per cent of pain management consultations end with a GP prescribing pain medication. Another 13 per cent will end in imaging, but less than 15 per cent can hope to be referred to an allied health professional.<sup>9</sup>

Unfortunately, this means that for the 3.374 million people living with chronic pain, access to best practice care is problematic at best, and fatal at worst. Understandably the physical, mental and emotional toll of chronic pain impacts every facet of patients' lives. The lack of pain specialist care and GPs with limited options to deal with chronic pain means that millions of Australians are falling through the cracks of the country's health system.

## CHRONIC PAIN AND MENTAL HEALTH



The impact on personal life is greatest in young adults, with **four in five** people with chronic pain aged 20-24 reporting interference in daily life



almost **one in three** Australian adults with severe or very severe pain have high or very high levels of psychological distress



Up to **two-thirds** of people with arthritis say their condition has affected them emotionally



Rates of depression are four times higher among people with chronic pain than people without pain



Research indicates there are strong links between anxiety, depression and chronic physical illness.

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## THE ISSUE:

### Affordability, access and quality of life

Untreated and poorly managed pain can devastate the lives of individuals and impact their relationships and ability to participate in work, education and the community.

Due to the complexity of chronic pain, it must be managed differently from acute pain, ideally through an interdisciplinary or multidisciplinary pain management approach. There is a growing consensus and research base that supports the importance of coordinated interdisciplinary management strategies to address pain, regarded as best practice, as well as strategies to prevent the escalation of acute pain to chronic pain.

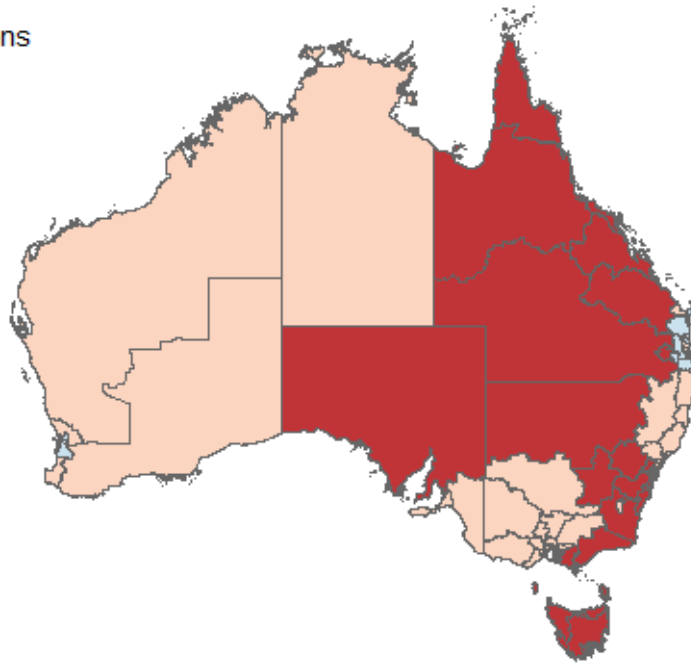
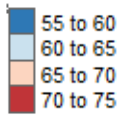
A multidisciplinary approach may include medical interventions and medication (which may or may not be required), but it primarily focuses on non-invasive and non-pharmacological treatments. Pharmacological treatments can be effective in reducing symptoms but are not always necessary and may not be sufficient alone to improve an individual's ability to function.

### Access to care

Patients with chronic pain can face long waiting times to access public services typically located in public hospitals, particularly in rural and remote areas. Among service providers, the provision and duration of allied-health pain management programs vary greatly. The level of service provision for children and rural patients is also notably lower than that reported for adults in urban areas.

Best practice multidisciplinary approach to pain management therefore remains inaccessible for most Australians. Nationwide, medications were used to manage chronic pain in an average 68.4 per cent of GP consultations involving someone attending for pain management. In terms of Medicare local regions, the highest rates were experienced in rural areas (72 per cent), followed by regional areas (68 per cent) and with the lowest rates recorded in metropolitan areas (65 per cent).

### Prescribed medications

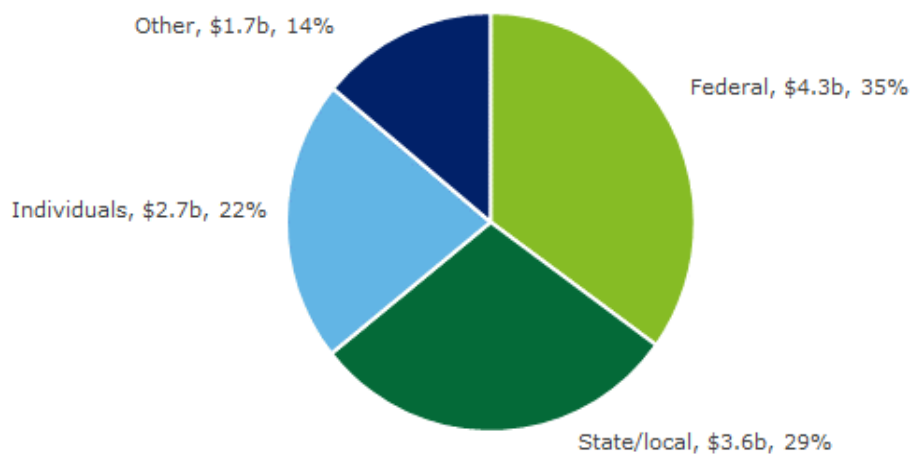


Source: Deloitte Access Economics analysis based on AIHW (2018).

### Affordability of care

As many people living with chronic pain opt to self-medicate, it is vital that they continue to have access to new and emerging drugs and technologies that are evidence-informed. Right now, people living with chronic pain bear about 22 per cent or \$2.7b of the costs associated with chronic pain.

Costs of chronic pain by source of funds, Australia 2018



Source: Deloitte Access Economics analysis.

These costs include over a billion dollars spent on medications, with half that cost borne by individuals.



Component	Federal	State/local	Individuals	Other	Total
Hospital	1,379.1	1,528.9	175.3	652.3	3,735.6
Out of hospital medical	712.3	241.2	254.4	133.3	1,341.2
Aged care	252.2	-	96.8	14.2	363.3
Other services	114.6	0.3	124.5	64.0	303.5
<b>Pharmaceutical</b>	<b>552.8</b>	<b>-</b>	<b>536.8</b>	<b>5.3</b>	<b>1,095.0</b>
<i>Conventional opioids</i>	<b>203.0</b>	<b>-</b>	<b>110.6</b>	<b>-</b>	<b>308.6</b>
<i>Atypical opioids*</i>	<b>110.6</b>	<b>-</b>	<b>39.8</b>	<b>-</b>	<b>150.3</b>
<i>Other medications</i>	<b>239.3</b>	<b>-</b>	<b>391.4</b>	<b>5.3</b>	<b>636.0</b>
Unallocated	1,263.9	1,806.5	1,474.1	842.2	5,386.8
<i>Non-admitted hospital services</i>	282.0	354.8	18.8	39.9	695.5
<i>Other health practitioners</i>	145.7	0.4	158.3	81.4	385.8
<i>Community health and other</i>	69.3	495.6	16.4	14.2	595.4
<i>Public health</i>	87.4	87.7	1.4	10.1	186.6
<i>All other medications</i>	45.0	-	654.1	7.4	706.5
<i>Dental services</i>	103.3	57.0	399.0	132.4	691.6
<i>Patient transport services</i>	20.8	190.8	29.2	21.8	262.6
<i>Aids and appliances</i>	57.8	-	195.3	55.5	308.6
<i>Administration</i>	152.1	60.8	1.5	100.1	314.6
<i>Research</i>	294.2	57.8	0.2	24.3	376.5
<i>Capital expenditure</i>	6.3	501.6	-	355.0	863.0
<b>Total</b>	<b>4,275.0</b>	<b>3,577.0</b>	<b>2,662.0</b>	<b>1,711.4</b>	<b>12,225.3</b>

The high cost of best practice pain management treatment adds additional stress to consumers already dealing with complex chronic pain.

## Quality of life

The daily challenges of chronic pain that are commonly described include loss of function, decreased enjoyment of normal activities, role change and relationship difficulties.<sup>10</sup>

As chronic pain is largely invisible, people living with pain can feel misunderstood and stigmatised by co-workers, friends, family, and even the medical profession.<sup>11</sup> If their condition cannot be explained in the typical framework of biomedicine, people with chronic pain can find their personal legitimacy is compromised, and they can experience barriers to accessing income support, health care and other support services.

Almost one third of Australian adults with severe or very severe pain experienced high or very high levels of psychological distress, which was around six times the rate of those with no pain. One in five Australian adults with severe or very severe pain also suffered depression or other mood disorders.<sup>12</sup>

Physical illness is prevalent in suicide deaths, and suicidal behaviour is found to be two to three times higher in those with chronic pain compared to the general population<sup>13</sup> and this may occur regardless of whether a co-morbid mental health disorder exists.<sup>14</sup>

# THE SOLUTION

## Consumer-centered approval processes

Right now, a new drug or treatment option cannot be subsidised for access in Australia without the recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC is required by legislation to consider both the cost and effectiveness of the medicines under review for listing on the PBS.

Existing mechanisms for consumer input to PBAC processes is limited, and inaccessible to grassroots consumers who are likely to be impacted by the determinations of the committee.

The involvement of consumers in the process of assessment varies across countries in terms of when and how consumers are involved. To improve patient and broader consumer involvement in the process, Painaustralia suggests that a useful starting point are the values developed by the Health Technology Assessment International (HTAi) [special interest group, for patient and citizen participation.](#)

Consumers and consumer peak bodies need to be engaged by PBAC through the approval process, to ensure that independent input is provided to inform their deliberations.

Painaustralia recently responded to a request from PBAC Deputy Chair Jo Watson for consumer input on the listing of belimumab for highly active autoantibody positive systemic lupus erythematosus (SLE), a chronic pain condition.

Painaustralia canvassed its consumer networks and provided input. PBAC did not eventually recommend the drug for listing, which was a disappointing outcome for many patients as belimumab was the only new therapy to be approved for this indication in 50 years.

Painaustralia notes the PBAC's acknowledgement of the clinical need for effective treatments for SLE, particularly for the group of patients who are not responding to current therapies, given the debilitating impact this condition can have on people's lives. This should highlight the crucial need to place an important emphasis on consumer input in these decision-making processes.

However, the limited timeframe and quick turnaround highlights the inadequacy of PBAC's current mechanisms to seek consumer input. This is a crucial barrier, especially where the committee is considering significant listings for drugs where currently there are few or limited consumer treatment options.

Similar concerns have also [been raised by people living with chronic migraines](#) over the [PBAC's rejection of Aimovig.](#)

### Recommendation

Painaustralia recommends that a useful starting point are the values developed by the Health Technology Assessment International (HTAi) special interest group, **for patient and citizen participation**



## CONCLUSION

There are few decisions in pharmacological management where there is only one unequivocally correct answer for everyone. This is especially true for the management of chronic pain, where at most clinical decision points, there are several possibilities that could be taken into account to address the issue or concern, including different treatments (e.g. different medications), non-pharmacological approaches, preventive strategies or lifestyle changes, in addition to the 'no active treatment' option, advice and reassurance.

Until we can provide consumers with access to affordable, best practice alternatives, medications will continue to play an important role in the management of chronic pain. It is important that our regulatory processes consider the needs for new and innovative pharmacological pathways for consumers. As many people living with chronic pain opt to self-medicate, it is vital that they continue to have access to new and emerging drugs and technologies that are evidence-informed. Importantly, it is vital that we consider more effective ways to ensure that consumer input is a crucial part of these approval processes.

Better understanding around the complexity of pain and best practice treatment that keeps pace with clinical and scientific advances remains a perennial challenge, together with remedying the barriers to receiving pain treatment and support. The PBAC cannot be across these new developments and a systematic approach to consumer input would address some of these current gaps.

Adopting international best practice in this area, notably the values developed by the Health Technology Assessment International (HTAi) special interest group, **for patient and citizen participation would provide more informed decision making that takes into account the important quality of life considerations for consumers who are the beneficiaries of these treatments.**

We hope that the Senate Committee finds our input to this Inquiry useful. We would be happy to present to the Inquiry or provide further information.

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