

# SCRIPTWISE

Consultation Submission:  
Prescription strong (Schedule 8)  
opioid use and misuse in  
Australia – options for  
a regulatory response  
March 2018

**Script  
Wise**

Preventing  
prescription  
medication  
misuse.

# Contents Page

## Table of Contents

RE: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response.....	3
<b>Contributions and Endorsements .....</b>	<b>4</b>
<b>Summary of Recommendations.....</b>	<b>5</b>
<b>Introduction.....</b>	<b>7</b>
<b>About ScriptWise .....</b>	<b>7</b>
ScriptWise strategic priorities 2018-2020 .....	8
Support for previous initiatives .....	8
<b>The Issue: prescription medication misuse.....</b>	<b>9</b>
<b>The benefits of a regulatory response.....</b>	<b>9</b>
Real-time monitoring .....	9
<b>The pitfalls of a regulatory response.....</b>	<b>11</b>
<b>Assessment of current proposed options.....</b>	<b>13</b>
Option 1: consider the pack sizes for strong (S8) opioids .....	13
Option 2: consider a review of the indications for strong (S8) opioids .....	13
Option 3: consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing.....	14
Option 4: strengthening of the Risk Management Plans for opioid products .....	14
Option 5: review of label warnings and revision to Consumer Medicines Information .	15
Option 6: consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes .....	15
Option 7: potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids .....	15
Option 8: increase health professionals’ awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain. ....	17
<b>Additional proposed regulatory responses .....</b>	<b>19</b>
Increase health professionals’ awareness of and training in treatments for opioid dependence and promote and support the uptake of community pharmacotherapy programs by primary care practitioners.....	19
Investigate regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction .....	20
Investigate regulatory options to reduce the cost and increase accessibility of allied health and pain management services for people with chronic non-cancer pain .....	20
Consider a full review of prescription medicines susceptible to misuse and dependency such as benzodiazepines and Schedule 4 opioids .....	21
Establish a National Working Group committed to addressing the harms associated with medicines susceptible to misuse and dependence.....	22
<b>Recommendations .....</b>	<b>22</b>
<b>Conclusion .....</b>	<b>25</b>

2 March 2018

Technical and Safety Improvement Section  
Therapeutic Goods Administration  
PO Box 100 Woden ACT 2606

Dear Sir/Madam,

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

On behalf of ScriptWise and our partners, I am pleased to accept this opportunity from the Therapeutic Goods Administration (TGA) to provide input on an effective regulatory response to Australia's current opioid crisis.

Following the up-scheduling of codeine, it is very encouraging to see the TGA recognise the broader issue of opioid misuse, dependence or addiction and overdose with this investigation into an appropriate regulatory response. Such a response is essential to prevent further overdose fatalities and misuse related to prescription opioids.

As this submission further details, ScriptWise and our partners have made several new recommendations for the TGA to consider in its regulatory response. The broad themes include:

- The importance of placing preventative strategies at the centre of efforts to address this crisis
- To reiterate our support for immediate action to instigate the most essential regulatory response: an integrated national real-time monitoring system.
- The need for a regulatory response around accessing treatment (including Medication-Assisted Treatment) for prescription medication dependence or addiction
- The important role of health professional training on dependence, addiction and pain management
- Support for a range of regulatory options outlined in the TGA's consultation paper to increase consumer awareness about the risks of long-term opioid use; and
- To build on the success of existing working groups led by ScriptWise in Victoria and Western Australia, to continue promoting coordinated communication, and supporting the work of Primary Health Networks

On behalf of ScriptWise and our partners, thank you for the opportunity to make this submission. I look forward to working with you in working together towards zero fatalities linked to prescription medication misuse, addiction or dependence.

Kind Regards,

[Redacted signature block]

## Contributions and Endorsements

ScriptWise would like to acknowledge and thank the following organisations for their input, feedback on and/or endorsement of this submission.

*This submission is endorsed by:*

MOVE muscle, bone & joint health

Hume Area Pharmacotherapy Network

La Trobe University School of Pharmacy and Applied Science (Bendigo)

*With thanks to the following contributors:*

WA Primary Care Quality Use of Medicines Group

WA Primary Health Alliance

Alcohol and Drug Foundation

ReturnToWorkSA

Access Health and Community

## Summary of Recommendations

**Recommendation 1:** The National Pharmaceutical Drug Misuse Framework for Action (2012-2015) needs to be updated to identify preventative strategies and priority areas for action

**Recommendation 2:** A national regulatory response should be investigated and implemented to improve access to treatment (including MAT) for opioid dependence or addiction

**Recommendation 3:** A national and integrated mandatory real-time monitoring system should be prioritised as a regulatory response to the prescription opioid crisis

**Recommendation 4:** Preventative strategies should be at the centre of efforts to address prescription opioid misuse

**Recommendation 5:** Public education and health professional training should be recognised and prioritised to address the underlying causes of the crisis

**Recommendation 6:** The NCCIWG should continue to be used as a strong mechanism to drive public education and health professional training

**Recommendation 7:** ScriptWise strongly supports implementation of Option 1

**Recommendation 8:** ScriptWise strongly supports implementation of Option 2

**Recommendation 9:** Further consultation with the appropriate peak medical bodies is necessary before Option 3 is further considered

**Recommendation 10:** ScriptWise supports Option 4 in principle but engagement and consultation with affected health organisations and professionals is necessary

**Recommendation 11:** ScriptWise strongly supports implementation of Option 5

**Recommendation 12:** ScriptWise supports extending the implementation of Option 5 to other potentially addictive Schedule 4 medications such as tramadol and benzodiazepines

**Recommendation 13:** ScriptWise strongly supports implementation of Option 6

**Recommendation 14:** The TGA should also consider expedited review of improved products for MAT options for opioid dependence or addiction

**Recommendation 15:** Further consultation with the appropriate peak medical bodies is necessary before Option 7 is further considered

**Recommendation 16:** Investigate the feasibility of mandatory education for health professionals in regard to best practice opioid prescribing.

**Recommendation 17:** ScriptWise strongly supports implementation of Option 8

**Recommendation 18:** Support PHNs to improve health practitioners' knowledge around the risks of Schedule 8 medications, appropriate treatment and support responses and effective pain management guidelines

**Recommendation 19:** Support the development of clinical pathways and shared care arrangements for patients which build on the resources already in use by local Primary Health Networks

**Recommendation 20:** Continue consultation and discussion with the NCCIWG on the appropriate implementation of regulatory responses

**Recommendation 21:** Increase health professionals' awareness of and training in treatments for prescription opioid addiction or dependence, and promote and support the uptake of community pharmacotherapy programs by primary care practitioners

**Recommendation 22:** Investigate the feasibility of mandatory education for health professionals in regard to MAT

**Recommendation 23:** Investigate regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction

**Recommendation 24:** Investigate regulatory options to reduce the cost and increase accessibility of allied health and pain management services for people with chronic non-cancer pain

**Recommendation 25:** Consider a full review of all prescription medicines linked to overdose fatalities (including S4 prescription opioids and benzodiazepines)

**Recommendation 26:** Include some S4 medications such as benzodiazepines in the scope of medicines monitored in the national real-time monitoring scheme

**Recommendation 27:** Establish a National Working Group committed to addressing the harms associated with medicines susceptible to misuse, dependence and addiction

## Introduction

Prescription opioid misuse, dependence, addiction, and overdose is a growing public health problem in Australia. This has been evidenced by a 15-fold increase in the prescribing and subsequent use of opioid painkillers and associated increases in hospital admissions, ambulance responses and overdose fatalities.

It is no surprise that concerns regarding prescription opioid dependence and addiction are increasingly being voiced by those affected, and within primary health care.

### *Key facts*

- Between 2006 and 2016 there was a 127 percent increase in the number of prescription-medication related deaths related to opioids
- From 2008 to 2014, there was also a 148 percent increase in prescription opioid deaths in rural and regional Australia.
- Prescription opioids, not heroin, now account for more than two-thirds of accidental opioid overdoses
- Australia recorded the highest number of drug-induced deaths last year since the heroin epidemic of the 1990s, largely due to prescription medications

While these statistics describe the severity of this crisis, as a consumer-driven organisation, ScriptWise is also very aware of the tragic toll this has taken on individuals, families and communities.

ScriptWise is pleased the Therapeutic Goods Administration has recognised the severity of this issue, and sought feedback on a regulatory framework best designed to address it.

## About ScriptWise

ScriptWise is a non-profit organisation dedicated to preventing prescription medication misuse, dependence and overdose in Australia. Formed in 2014, ScriptWise seeks to amplify the voices of the alarming number of families and individuals affected by this issue.

In the words of ScriptWise's Founding Patron, [REDACTED], who lost his son [REDACTED] an accidental prescription medication overdose: "We are motivated by a strong desire to prevent this from happening to any other family in Australia."

**Our vision:** zero overdose fatalities caused by prescription medication misuse, addiction and dependence.

**Our mission:** to be the national body that raises awareness and educates all Australians to prevent prescription medication misuse and overdose fatalities

## ScriptWise strategic priorities 2018-2020

ScriptWise focusses on addressing the root causes of this complex and multifaceted issue through primary prevention strategies such as:

- **engaging and educating local communities** on the safe and effective use of prescription medications
- **collaborating to shape policy solutions** that help improve Australians' quality of life such as the implementation of an effective real-time prescription monitoring system across Australia
- **conducting research** to understand the costs associated with, underlying causes of, and potential solutions for, addressing misuse of prescription medications

## Support for previous initiatives

ScriptWise would like to acknowledge and provide support for the previous recommendations and guidelines for action as outlined in the:

- National Pharmaceutical Drug Misuse Framework for Action (2012-2015), and
- The Opioids Roundtable
- National Drug Strategy 2017-2026

The National Pharmaceutical Drug Misuse Framework for Action (2012-2015), in particular, has been an important blueprint for action. As a milestone document, the Framework outlines the severity of this crisis, and the subsequent need to address it, and provides a comprehensive analysis of the variety of strategies needed to reduce fatalities related to prescription medication misuse and dependence or addiction.

An updated framework should place greater emphasis on the need for non-pharmaceutical approaches to managing pharmaceutical misuse, to help alleviate additional pressure on medical professionals. It is clear that this Framework urgently needs to be updated, as its priorities could be very helpful in guiding processes such as these changes to regulations in Australia.

Australia's National Drug Strategy 2017-2026 has also identified both 'Opioids' and 'Non-medical use of pharmaceuticals' as priorities to address. The strategy outlines that harms from legally available products such as pharmaceuticals can be reduced by regulating supply and "Increasing training and support for prescribers and those at the point of supply."

Given the prioritisation of a response to pharmaceutical use in this strategy, it is clear that a more detailed, comprehensive and prevention-focussed Framework for Action is urgently needed, given the previous version expired three years ago.

**Recommendation 1:** The National Pharmaceutical Drug Misuse Framework for Action (2012-2015) needs to be updated to identify preventative strategies and priority areas for action.

## The Issue: prescription medication misuse

### The benefits of a regulatory response

There are many benefits associated with a regulatory response to address the harms associated with prescription opioid misuse, addiction and dependence. As the [World Health Organization notes](#), pharmaceuticals must be regulated due to the fact that consumers are not able to assess the “efficacy, safety, and the quality of pharmaceuticals before buying them”. Regulations are an essential tool to ensure Australians benefit from quality, effective and safe prescription medications. Given the known issues associated with prescription opioids, and the increasing number of related deaths, it is clear that the relevant powers of regulatory bodies such as the TGA must be used wherever possible to prevent further harms.

The TGA’s consultation paper suggests that regulatory approaches may have

*“greater impact on unsanctioned (including excessive) opioid use while educational approaches may impact more on inappropriate prescribing of opioids.”*

While ScriptWise agrees with this statement, it is also important to stress that regulatory approaches to this issue may also be relevant to treatment for the common harms associated with long-term use of Schedule 8 opioid medications.

Despite recognition of this within the National Pharmaceutical Drug Misuse Framework for Action (2012-2015), the current TGA response does not consider regulatory responses essential to improving access and removing barriers preventing effective treatment of prescription opioid dependence or addiction. The addition of this essential regulatory action is a key component of ScriptWise’s submission.

National regulation on this issue could have the added benefit of standardising treatment options available across Australia. Currently, there is inconsistency between States on regulations regarding how a patient is able to receive Medication-Assisted Treatment (MAT). More needs to be done to remove these barriers and improve access to treatment.

The suggested regulatory approaches are detailed further in the ‘Additional Regulatory Response Proposals’ section of this submission. As the TGA’s consultation paper acknowledges, it is crucial to recognise that a broader regulatory response is needed to address this issue.

**Recommendation 2:** A national regulatory response should be investigated and implemented to improve access to treatment (including MAT) for prescription opioid dependence or addiction.

### Real-time monitoring

ScriptWise acknowledges the Federal Government’s recognition of the importance of a national real-time monitoring system through its commitment of \$16 million to take this necessary next step.

The implementation of real-time monitoring of prescription medications has also been recognised as evidence of good practice regarding supply reduction in the National Drug Strategy 2017-2026.

Real-time monitoring would prevent many Australians from dying by allowing primary care providers to make informed decisions around their patients' medications. It will also enable doctors and pharmacists to start a potentially life-saving conversation with their patients about the many effective treatment options available for dependence and addiction issues.

ScriptWise is pleased to join the many peak health organisations advocating for this change including the Australian Medical Association, the Royal Australian College of General Practitioners, the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia and many other health professionals and organisations.

ScriptWise will continue to advocate for a real-time monitoring system dedicated to addressing this issue. It would be most beneficial if the TGA and all members of the Nationally Coordinated Codeine Implementation Working Group (NCCIWG) could be involved in aiding the Federal government to roll out this national system. This would necessitate action on these key elements:

- A commitment by remaining states and territories to fund an integrated real time prescription monitoring system, which will include the scope of medicines as proposed in the Victorian's SafeScript system
- Examination of how the system will interact and potentially integrate with existing real-time monitoring systems in Tasmania and soon Victoria
- The implementation of a well-coordinated national public awareness campaign to improve health literacy and increase understanding of prescription medication use, misuse and overdose
- The provision of appropriate training for health professionals around the system and its software
- Consideration of mandatory training for health professionals on the effective treatment of prescription medication dependence (including MAT) and patient pathways
- Designation of monitoring as a therapeutic, and not punitive, tool. Each individual's complex needs must be considered, and blanket approaches to prescribing avoided

A national real-time monitoring system is one of the most important regulatory changes which can be implemented to reduce overdose deaths and provide pathways for those needing treatment for dependence or addiction issues. The strength and unity of the medical community in support of this system indicates that its immediate implementation would be met with significant support.

It is also important to note that while ScriptWise further details its support for most of the options presented by the TGA for consideration, it is this broader regulatory change which is most urgent to prevent prescription medication-related deaths.

The lived experience of one of ScriptWise's key ambassadors, [REDACTED] demonstrates the necessity of such a system. Margaret and her husband John lost

their son ██████ to an accidental prescription medication overdose when he was only 34 years old. At 19, ██████ became addicted to prescription opioids after suffering life-threatening injuries in a car accident which led to him enduring long-term hospitalisation. The absence of a nation-wide database detailing his prescription history allowed ██████ to go from doctor to doctor and even travel long distances, often interstate, to seek more medications.

Tragically, ██████ and ██████ story is just one of the many painful stories behind the statistics, and further demonstrates the urgent need not only for real-time monitoring, but a cultural shift to recognise the severity of this public health crisis.

**Recommendation 3:** A national and integrated mandatory real-time monitoring system should be prioritised as a regulatory response to the prescription opioid crisis

### The pitfalls of a regulatory response

ScriptWise agrees with the TGA's consultation paper's assessment that:

*“Changes in prescriber behaviour and changes in community expectations about the use of opioids in management of chronic non-cancer pain will have greater impact on appropriate prescription and unsanctioned use of opioids” (p11).*

It is clear that cultural and behaviour change will be key to successfully addressing prescription opioid misuse within Australia. This is the reason ScriptWise's work within this area focusses on preventative strategies.

Health professionals, for example, are aware of ingrained social attitudes which see people turn to a 'quick fix' in order to continue their daily lives, and an increasing intolerance towards experiencing pain, as underlying culturally-influenced reasons for Australians' reliance on prescription opioids.

These observations clearly correspond with current research which places pain management within a broader context in which it is viewed as not only physical in nature. Instead, it has social, psychological, behavioural and financial components.

Solutions to address these underlying causes in order to influence behaviour change are outside the scope of regulatory mechanisms, and must be addressed by public education, skills development, increased awareness of self-help options and improved health literacy around pain management.

Too many Australians are unaware of the risks associated with using these medications. More than one-quarter of Australians think non-medical use of pharmaceuticals is acceptable (a 23 percent increase since 2013), and about 1 million Australians reported recent non-medical use of a pharmaceutical. It is clear that public awareness and education campaigns must be at the centre of efforts to reduce prescription opioid misuse, dependence or addiction.

Similarly, in terms of changing prescriber behaviour and increasing adherence to best practice care in pain management, it is clear that education and training for health care professionals will also be necessary.

Currently, Australia ranks 8<sup>th</sup> among the world's top users of prescription opioids with approximately 20,000 doses prescribed for every 1 million people. Moreover, prescribing practices are not currently standardised across the country with some areas seeing rates of opioid prescription up to ten times higher than others. There is also a need for individualised pain management plans to be in place at the point when a patient is first prescribed an opioid. This plan must be jointly developed between the patient and the prescriber.

Public awareness raising and education efforts are largely outside of the TGA's regulatory powers. ScriptWise does, however, agree with the TGA's conclusion that they are probably more important than regulatory responses to address the issues.

**Recommendation 4:** Preventative strategies should be at the centre of efforts to address prescription opioid misuse

**Recommendation 5:** Public education and health professional training should be recognised and prioritised to address the underlying causes of the crisis

To this end, it would be advisable for the NCCIWG to continue to co-operate and collaborate in pursuit of these aims. Codeine rescheduling similarly involved providing essential information to a range of different audiences. The centralisation of key messages around this issue provided consistency across communication modes and in the media.

However, as discussed further later within this submission, there are additional improvements to be made regarding membership and leadership of this Group in order to maximise its effectiveness.

**Recommendation 6:** The NCCIWG should continue to be used as a strong mechanism to drive public education and health professional training

## Assessment of current proposed options

### Option 1: consider the pack sizes for strong (S8) opioids

ScriptWise strongly supports further investigation, and potentially implementation, of Option 1. Option 1 would see sponsors “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 days) for treatment of people with chronic pain due to malignancy.”

ScriptWise agrees with evidence provided by the TGA that the continued use of strong prescription opioids for extended periods of time may lead to dependence and addiction.

A recent US study, for example, has found that with one refill of an opioid prescription, the rate of misuse more than doubled. Each prescription refill increased the rate of misuse by 70.7 percent. There is also evidence that chronic opioid use can lead to ‘hyperalgesia’ where patients become more sensitive to pain over time.

From a consumer perspective, changes in the size of the pack prescribed will provide more concrete guidance regarding the risks associated with using too many prescription opioids over a long period of time. If consumers find they need more medication, a visit to their GP will increase their chances of being provided with safer acute and chronic pain relief alternatives. Moreover, it will have the added effect of preventing consumers from being left with packs of medications in their cupboards which can pose a significant risk to others in their household as well.

Ideally, implementation of this option should follow the introduction of real-time monitoring so as to minimise the risk of misuse.

**Recommendation 7:** ScriptWise strongly supports implementation of Option 1

### Option 2: consider a review of the indications for strong (S8) opioids

ScriptWise similarly supports the review of the current indications for strong opioid products and their alignment with current clinical guidelines for the appropriate use of these products.

The latest general practice data show that an opioid is prescribed for three in four cases (72%) of multisite pain management. The rate of opioid prescribing for chronic non-cancer pain is a major contributing factor – despite evidence of ineffectiveness for long-term pain. As identified previously, there is also a significant risk of abuse, dependence and overdose.

ScriptWise supports NPS Medicinewise Choosing Wisely recommendations released last year which urge doctors to “not prescribe opioids for the treatment of acute or chronic pain” without conducting a thorough investigation and considering the alternatives. This is based on evidence that the risks of using these medications may

outweigh the benefits. There is insufficient evidence that the pain relief provided by opioids is sustained in the long-term. Indications for use of opioids for non-cancer pain (particularly regarding high strength opioids such as fentanyl) would therefore be very beneficial for healthcare providers and the community.

Hospitals would similarly benefit from updated opioid prescribing and discharge policies. This is a unique opportunity to prevent potential harms in the future, as patients are often first given prescription opioids in this setting.

**Recommendation 8:** ScriptWise strongly supports implementation of Option 2

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

ScriptWise notes that Option 3 has been quite contentious within the medical community. It has been suggested that changes related to the restriction of specialist/authority prescribing may unduly affect GPs working in community care settings and diminish the powers of those most suited to address this issue. It may also affect demand for specialists who may already be finding it difficult to meet local needs.

ScriptWise would like to highlight that any proposed options such as this are developed in consultation with consumers, relevant stakeholders and peak medical bodies to ensure all potential ramifications of such decisions are considered. Particular consideration should be given to the needs of, and implications for, health professionals working in regional and remote locations.

**Recommendation 9:** Further consultation with the appropriate peak medical bodies is necessary before Options 3 is further considered

**Option 4: strengthening of the Risk Management Plans for opioid products**

ScriptWise offers in-principle support for the strengthening of Risk Management Plans for prescription opioid products.

As the TGA's consultation paper notes, organisations which could potentially create Continuing Professional Development opportunities such as the RACGP and NPS MedicineWise, are most suited to provide comment on the reality of implementing such changes.

There is also a need for hospitals to implement opioid prescribing and opioid discharge policies. Patients are often first introduced to prescription opioids in the emergency room, and efforts within Australia and abroad to reduce prescribing within the hospital setting have been very successful.

However, ScriptWise fully supports more holistic education for health professionals regarding prescription opioid management and prescribing. This is further discussed in Option 8.

**Recommendation 10:** ScriptWise supports Option 4 in principle but engagement and consultation with affected health organisations and professionals is necessary

#### Option 5: review of label warnings and revision to Consumer Medicines Information

ScriptWise supports the placement of warnings on prescription opioid product packaging to identify the risks of dependence or addiction, and the lack of efficacy in long-term treatment of non-cancer pain. Ideally, ScriptWise would like to see these warnings extended to include other potentially addictive prescription medications which are currently not Schedule 8 medications, such as tramadol and other benzodiazepines.

ScriptWise also supports the review of the CMI to provide greater emphasis on risks of potential dependence or addiction. It will be necessary to involve consumers to ensure that the message and language utilised in warnings will effectively reach the target audience.

A comprehensive approach and range of strategies to support behaviour change must also be considered in addition to labelling given the potential for consumers to ignore or not read warning labels.

**Recommendation 11:** ScriptWise strongly supports implementation of Option 5

**Recommendation 12:** ScriptWise supports extending the implementation of Option 5 to other potentially addictive Schedule 4 medications such as tramadol and benzodiazepines

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

ScriptWise supports the expedition of TGA review of improved products for pain relief and opioid antidotes.

ScriptWise would also like to extend this expedited TGA review to improved products for medically-assisted treatment options for prescription opioid dependence or addiction as well. Such expedition should not, however, compromise relevant safety requirements.

**Recommendation 13:** ScriptWise strongly supports implementation of Option 6

**Recommendation 14:** The TGA should also consider expedited review of improved products for MAT options for opioid dependence or addiction

#### Option 7: potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids

As noted in response to Option 3, ScriptWise would caution against any changes to prescribing for particular populations or classes of medical practitioners without

comprehensive engagement with relevant representative bodies, and in particular, without consulting health professionals in regional areas.

ScriptWise strongly supports Australia following the US FDA's lead by considering mandatory education for health professionals in regard to best practice opioid prescribing and multidisciplinary pain management.

However, a more thorough analysis of the potential consequences of mandatory education, such as burn-out or disinterest from health professionals already adhering to best practice, would be necessary prior to its introduction. It would also be valuable to consult professional groups on the best ways to reach high prescribers within the community.

The National Pharmaceutical Drug Misuse Framework for Action (2012-2015) also supports "Enhancing education programs for quality prescribing for conditions such as pain...at all levels from undergraduate through to post-graduate and in service." The Framework's emphasis on education stems from its recognition that health service providers encounter issues such as prescription medication dependence or addiction in clinical practice at a disproportionate rate to which they're included in practitioner education programs at all levels.

Moreover, despite the media coverage around 'doctor-shoppers' (stigmatising terminology often used by journalists), the Victorian Coroners Court found that in 7 out of 10 pharmaceutical drug overdose deaths, the deceased had visited only one GP. This evidence suggests that enhanced education around the quality of prescribing is necessary from undergraduate to post-graduate education programs.

There has been recognition within Australia that undergraduate and post-graduate courses do not currently provide the necessary training regarding the relatively new issue of prescription medication dependence and addiction. Embedding training and exposure to treatment of opioid dependence or addiction with pharmacotherapy at an undergraduate level is essential. This will help to normalise treatment in primary care and reduce stigma by framing substance use disorders as relapsing and remitting chronic diseases. Health professionals should be required to provide treatment where appropriate, with referral options to specialist services as per other medical conditions.

It may also be useful to provide young doctors with more understanding that modern medicine has inadvertently played a role in facilitating increased dependence on opioid medications, and the harms arising from their use.

It is also essential that health professionals understand the risk factors for developing a chronic pain condition and shift towards active management and evidence-based interventions. MOVE's work has demonstrated that patients currently do not source information about alternative strategies to tackle pain from their doctors. Health professional training and education must therefore also include both pharmaceutical and non-pharmaceutical treatment options.

Unfortunately, ScriptWise has also heard anecdotes from patients who developed opioid dependency or addiction which highlight the need for more education for

health professionals regarding appropriate prescribing and pain management options.

**Recommendation 15:** Further consultation with the appropriate peak medical bodies is necessary before Option 7 is further considered

**Recommendation 16:** Investigate the feasibility of mandatory education for health professionals in regard to best practice opioid prescribing.

**Option 8: increase health professionals' awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain.**

ScriptWise is extremely supportive of regulatory efforts to increase health professionals' awareness of alternatives to both S4 and S8 opioids in the management of chronic pain.

As already articulated in response to Option 7, ScriptWise supports the inclusion of mandatory education for all for health professionals in regard to best practice opioid prescribing and multidisciplinary pain management. Ideally, health professional education around responsible prescribing would also be combined with training regarding the implementation of a national mandatory real-time monitoring system. Health professionals should be required to provide treatment for dependence or addiction issues where appropriate, with referral options to specialist services as per other medical conditions.

ScriptWise also strongly advocates for the continued and central role of Primary Health Networks to improve health practitioners' knowledge around the risks of Schedule 8 medications, effective pain management guidelines and how to recognise and respond to harmful prescription medication use.

ScriptWise also supports the utilisation of 'clinical pathways' for patients. It is important to note that many PHNs have already developed, or are in the process of developing, localised resources to support appropriate clinical pathways for patients.

There is also scope for these pathways to be embedded in medical software. Continued support for the sharing and development of effective clinical pathways, and shared care arrangements between primary care and drug and alcohol specialist services are recommended.

Finally, ScriptWise would like to express support for the continuation of the NCCIWG as a national communications network providing key information on this issue. Consideration could also be given to the inclusion of a national Primary Health Network representative in the membership.

**Recommendation 17:** ScriptWise strongly supports implementation of Option 8

**Recommendation 18:** Support PHNs to improve health practitioners' knowledge around the risks of Schedule 8 medications, appropriate treatment and support responses and effective pain management guidelines

**Recommendation 19:** Support the development of clinical pathways and shared care arrangements for patients which build on the resources already in use by local Primary Health Networks

**Recommendation 20:** Continue consultation and discussion with the NCCIWG on the appropriate implementation of regulatory responses

## Additional proposed regulatory responses

Increase health professionals' awareness of and training in treatments for opioid dependence and promote and support the uptake of community pharmacotherapy programs by primary care practitioners.

In a similar approach to the TGA's consultation submission's Option 8, ScriptWise supports increased efforts to ensure health professionals are educated in the treatment of opioid dependence.

As the National Drug Strategy 2017-2026 outlines

*"Treatment options and support services have shown to be highly effective in helping reduce risky alcohol, tobacco and other drug use as well as related problems for individuals and the broader community" (p9)*

Throughout ScriptWise's regional roadshow around Victoria last year, it became clear that a recurring problem identified by key stakeholders within these areas was a lack of prescribers and dispensers of MAT, despite evidence of its effectiveness and demand for the service. Further to this, there is great stigma towards patients suffering from dependence or addiction and reluctance of health professionals to become a prescriber and/or dispenser.

Research has identified that stigma can play a large part in preventing both prescribers and community members from utilising MAT services. Many GPs, particularly in rural areas, are concerned about patients exhibiting difficult behaviours regarding pharmacotherapy.

It is essential that all health professionals are provided with the necessary training in how to appropriately identify and treat people with prescription medication dependence issues, including using MAT. Increased efforts to encourage potential prescribers to feel comfortable providing these services, and support them once they do, will be essential to treat the increasing number of Australians affected by this issue.

The Victorian Coroners Court has acknowledged this issue, noting that

*"because of demand for ORT doctors' services, they rarely have time to do anything other than treat opioid dependence, and therefore must by necessity direct patients to other doctors for treatment of any other conditions."*

**Recommendation 21:** Increase health professionals' awareness of and training in treatments for opioid dependence, and promote and support the uptake of community pharmacotherapy programs by primary care practitioners

**Recommendation 22:** Investigate the feasibility of mandatory education for health professionals in regard to MAT

## Investigate regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction

ScriptWise supports further investigation of regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction, including the potential to further or fully subsidise treatments under the PBS.

The benefits of MAT for opioid dependence or addiction have been well documented and proved to be clinically effective and life-saving in reducing the need for inpatient detoxification services for individuals. The cost of MAT for patients should therefore be equitable in relation to other medication treatments for chronic diseases.

The Centre for Research Excellence into Injecting Drug Use policy report suggests that the daily MAT dispensing fee can range from \$1.50 to \$10, averaging to an annual cost which could exceed \$1,800 and be as high as \$3,640. This is one of the most prohibitive issues regarding adherence to pharmacotherapy treatment. It also puts the financial burden of treatment on to community members who are often facing hardships due to their dependency or addiction issues (for example, unemployment or housing issues).

Investigation into regulatory and financial options to improve access to MAT is therefore necessary. Options which could be considered include: further or fully subsidising treatments under the PBS; remunerating providers appropriately; and creating a new MBS item – a ‘substance use disorder care plan’ with appropriate subsidy similar to a mental health care plan or chronic disease management plan.

Moreover, it is important to recognise that the face of opioid dependence/addiction has changed in Australia. This will likely necessitate changes in how MAT options are discussed and promoted within communities.

**Recommendation 23:** Investigate regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction

## Investigate regulatory options to reduce the cost and increase accessibility of allied health and pain management services for people with chronic non-cancer pain

It is well-recognised that effective management of chronic non-cancer pain often involves multidisciplinary care. This includes a particular emphasis on non-pharmaceutical treatment and management options such as physiotherapy, daily exercise, behavioural changes and psychological therapies such as Cognitive Behavioural Therapy (CBT).

According to PainAustralia, one in five Australians are living with pain and the economic cost of chronic pain in 2007 was estimated at more than \$34 billion.

Given the size of this issue, and the recognised importance of educating health professionals in best-practice pain management strategies, it is essential that the cost and availability of non-pharmaceutical treatments are not prohibitive.

Similarly, patients would also benefit from more transparency around the waiting list for pain clinics and other specialised services. Currently, patients with chronic conditions are only eligible for Medicare rebates on five allied health services per calendar year as part of a Chronic Disease Management (CDM) plan.

**Recommendation 24:** Investigate regulatory options to reduce the cost and increase accessibility of allied health and pain management services for people with chronic non-cancer pain

Consider a full review of prescription medicines susceptible to misuse and dependency such as benzodiazepines and Schedule 4 opioids

Recently, the UK Health Minister Steve Brine requested Public Health England make recommendations outlining what it thinks the government and NHS should do to limit dependency or addiction issues. The review is wide-ranging, including medicines such as:

- Benzodiazepines (anti-anxiety medications) such as Valium, Ativan and Xanax.
- Z-drugs, a similar class of drugs often used to treat insomnia.
- Antidepressants.
- Opioid pain-relieving drugs.
- Pregabalin, which is used for anxiety, insomnia and nerve pain.
- Gabapentin, an anticonvulsant used to treat epilepsy

Given the severity of the prescription medication overdose crisis in Australia, it is clear that a similar review in Australia would likely be warranted.

According to a [recent report by the AIHW](#), the number of drug-induced deaths involving benzodiazepines increased by 168 percent between 2006 and 2016. Diazepam and Temazepam were the most commonly prescribed benzodiazepines in 2014–15 (1.81 million prescriptions of Diazepam and 1.57 million of Temazepam). A review into these medications would be justified based on the amount of harm caused.

Moreover, the Victorian Coroners Court has indicated its support for both the [upscheduling of benzodiazepines to Schedule 8](#) and their [inclusion in a real-time monitoring system](#). Similarly, research conducted by the Austin Hospital recommended SafeScript (Victoria’s real-time prescription monitoring system to be rolled out in 2018) include some S4 medications such as benzodiazepines given people could switch to using medicines not covered by the system (the ‘squeezed balloon effect’). This review should therefore also consider whether all benzodiazepines should be rescheduled.

**Recommendation 25:** Consider a full review of all prescription medicines linked to overdose fatalities (including prescription opioids and benzodiazepines)

**Recommendation 26:** Include some S4 medications such as benzodiazepines in the scope of medicines monitored in the national real-time monitoring scheme

## Establish a National Working Group committed to addressing the harms associated with medicines susceptible to misuse and dependence

ScriptWise wishes to acknowledge the valuable role of the NCCIWG in managing the codeine rescheduling transition. It was an important vehicle for peak bodies and relevant health organisations to cooperate on effective, unified communication of the changes and facilitate collaboration between national and state-based organisations.

ScriptWise recognises, however, with the broader scope of these regulatory responses, there are new and important stakeholders to include in discussion and planning efforts. In particular, ScriptWise suggests the need to include primary health networks across Australia, service providers, and migrant and Aboriginal health organisations in these broader discussions.

It is essential that there is a more coordinated and collaborative approach to addressing harms associated with prescription medications. This could be aided by the appointment of an organisation to lead the development of health professional information and training, as well as community education.

In order to ensure the community is not bombarded by different information from different providers, a centralised information hub hosting information which is collaboratively created would be very useful.

**Recommendation 27:** Establish a National Working Group committed to addressing the harms associated with medicines susceptible to misuse, dependence and addiction

## Recommendations

ScriptWise would like to reiterate support for both regulatory and non-regulatory action to reduce the harms associated with prescription opioids within Australia. A preventative approach by national regulatory and legislative bodies is essential if Australia is to avoid following the US into a prescription opioid epidemic.

While the recommendations below are wide-ranging and support many of the Options outlined in the TGA's consultation paper, it is important to recognise the urgent need for one regulatory response in particular: a national real-time monitoring system. ScriptWise supports the prioritisation of action to implement a mandatory, integrated system as soon as possible.

Similarly, options related to increasing health professionals' knowledge and improving their capacity to respond underpin the success of other regulatory changes and their immediate implementation is essential.

Below is the full list of the recommendations within this report.

**Recommendation 1:** The National Pharmaceutical Drug Misuse Framework for Action (2012-2015) needs to be updated to identify preventative strategies and priority areas for action.

**Recommendation 2:** A national regulatory response should be investigated and implemented to improve access to treatment (including MAT) for opioid dependence or addiction.

**Recommendation 3:** A national and integrated mandatory real-time monitoring system should be prioritised as a regulatory response to the prescription opioid crisis

**Recommendation 4:** Preventative strategies should be at the centre of efforts to address prescription opioid misuse

**Recommendation 5:** Public education and health professional training should be recognised and prioritised to address the underlying causes of the crisis

**Recommendation 6:** The NCCIWG should continue to be used as a strong mechanism to drive public education and health professional training

**Recommendation 7:** ScriptWise strongly supports implementation of Option 1

**Recommendation 8:** ScriptWise strongly supports implementation of Option 2

**Recommendation 9:** Further consultation with the appropriate peak medical bodies is necessary before Options 3 is further considered

**Recommendation 10:** ScriptWise supports Option 4 in principle but engagement and consultation with affected health organisations and professionals is necessary

**Recommendation 11:** ScriptWise strongly supports implementation of Option 5

**Recommendation 12:** ScriptWise supports extending the implementation of Option 5 to other potentially addictive Schedule 4 medications such as tramadol and benzodiazepines

**Recommendation 13:** ScriptWise strongly supports implementation of Option 6

**Recommendation 14:** The TGA should also consider expedited review of improved products for MAT options for opioid dependence or addiction

**Recommendation 15:** Further consultation with the appropriate peak medical bodies is necessary before Option 7 is further considered

**Recommendation 16:** Investigate the feasibility of mandatory education for health professionals in regard to best practice opioid prescribing.

**Recommendation 17:** ScriptWise strongly supports implementation of Option 8

**Recommendation 18:** Support PHNs to improve health practitioners' knowledge around the risks of Schedule 8 medications, appropriate treatment and support responses and effective pain management guidelines

**Recommendation 19:** Support the development of clinical pathways and shared care arrangements for patients which build on the resources already in use by local Primary Health Networks

**Recommendation 20:** Continue consultation and discussion with the NCCIWG on the appropriate implementation of regulatory responses

**Recommendation 21:** Increase health professionals' awareness of and training in treatments for opioid dependence and promote and support the uptake of community pharmacotherapy programs by primary care practitioners

**Recommendation 22:** Investigate the feasibility of mandatory education for health professionals in regard to MAT

**Recommendation 23:** Investigate regulatory options to reduce the cost and increase accessibility of MAT options for opioid dependence or addiction

**Recommendation 24:** Investigate regulatory options to reduce the cost and increase accessibility of allied health and pain management services for people with chronic non-cancer pain

**Recommendation 25:** Consider a full review of all prescription medicines linked to overdose fatalities (including prescription opioids and benzodiazepines)

**Recommendation 26:** Include some S4 medications such as benzodiazepines in the scope of medicines monitored in the national real-time monitoring scheme

**Recommendation 27:** Establish a National Working Group committed to addressing the harms associated with medicines susceptible to misuse, dependence and addiction

ScriptWise would like to acknowledge that these recommendations are consistent with the Advisory Committee for Medicines recommendations on the earlier version of the TGA's consultation paper.

## Conclusion

ScriptWise and our partners are pleased to present the TGA with this submission to address the increasing harms associated with prescription opioids. Please contact

[REDACTED]  
[REDACTED] to discuss any of the submission's recommendations.

Thank you to the TGA for this opportunity to discuss an effective regulatory response to the current prescription opioid crisis. Together, we can work towards zero overdose fatalities relating to prescription medication misuse.

