

painaustralia

**SUBMISSION TO DEPARTMENT OF HEALTH AND HUMAN SERVICES,
VICTORIAN GOVERNMENT**

Regulatory impact statement and proposed regulations for Safescript
Victoria's real-time prescription monitoring system

MARCH 2018

Executive Summary

Painaustralia welcomes the opportunity to provide feedback to the Victorian Government on the Regulatory Impact Statement (RIS) and proposed new regulations relating to the implementation of SafeScript, Victoria's real-time prescription monitoring system.

While we strongly support the realisation of a national real-time monitoring system to bring about nationally consistent and systemic change to address misuse of prescription medicines, we welcome the Victorian Government's commitment to implement a fit-for-purpose system.

Effective regulation of access to medications is critical to prevent misuse of pain medications and related harms, but misuse also highlights the urgent need for a national and holistic strategy to better prevent, treat and manage pain. Real-time prescription monitoring systems should be considered part of a wider whole-of-governments approach that includes the adoption of a national pain strategy.

With a 30% increase in opioid prescribing between 2009 and 2014¹ and opioid overdoses including accidental overdoses at record levels in Australia, these medications are being increasingly used to treat non-cancer chronic pain despite limited evidence of their efficacy or safety.²

At least one in five Australians experience chronic non-cancer pain (CNCP)³ and it's the reason for up to 40% of adult general practice consultations.⁴ Access to alternative treatment options for those living with chronic pain is critical to reducing misuse of medications.

We urge the Victorian Government to carefully consider the specific issues faced by people living with these conditions in its policy development and regulatory settings.

SafeScript can play an important role by identifying patients at risk of drug misuse and unlikely to be accessing pain services, providing a possible gateway to a pain management pathway. It will also identify at risk health practitioners and can link them to education to enhance clinical practice.

It can also gather information on the profile of those at risk of harm including demography and location and inform the delivery of health policy, including the planning and delivery of pain services.

We note the commitment from the Australian Government to implement a national real-time prescription monitoring system proposed for rollout by the end of 2018.

It is likely SafeScript will be a catalyst and potential model for the eventual roll out of a national system. Therefore, it is critical the design and implementation of the system is informed by the engagement and involvement of a wide range of stakeholders, including health consumers.

About Painaustralia

Painaustralia is the leading national peak body to develop and inform national pain strategies and policies and was formed in 2011 to work with government, health professional and consumer stakeholders to facilitate implementation of the National Pain Strategy.

Painaustralia's primary mission is to improve the quality of life for people with pain and their families and minimise the burden of pain on individuals and the community. Effectively tackling pain – as a complex physical, psychological and environmental condition – is in the interest of every Australian.

With over 150 members and partners across a diverse range of stakeholders including consumers, medical specialists, pharmacists, academics, carers, pharmaceutical companies, allied health professionals and others with an interest in pain, Painaustralia consults our network widely to inform practical and strategic solutions to address this complex and widespread issue.

Painaustralia also provides essential sources of information for consumers, medical practitioners and researchers.

Summary of Recommendations

PainAustralia recommends that in implementing SafeScript, the Victorian Government:

- Recognise the relationship between the misuse of pain medications and the need for greater access to best practice, multidisciplinary and holistic pain management services for chronic pain patients and the urgent need to implement a National Pain Strategy.
- Recognise the role of SafeScript in providing vital data and information to inform health policy, particularly as it relates to the delivery of pain services, early intervention and support.
- Include modules on health pathways and best practice pain management in training provided prior to the implementation of SafeScript.
- Recognise the role of SafeScript in identifying at risk health practitioners who require mandatory training in quality use of medicines and best practice pain medicine.
- Ensure SafeScript does not increase stigma experienced by people with chronic pain and is accompanied by a strong consumer awareness campaign to increase understanding of pain, pain management and the quality use of medicines
- Understand and address widespread and poor pain management practices in residential aged care to improve quality use of medicines and quality of life in those facilities, noting they are deemed exempt in the Regulatory Impact Statement (RIS).
- Engage and consult a wide range of stakeholders including consumers groups and national health groups about the design, delivery and evaluation of SafeScript.

(1) Intersection between Real-Time Monitoring and Multidisciplinary Pain Management

SafeScript and a National Pain Strategy

With a 30% increase in opioid prescribing between 2009 and 2014⁵ and opioid overdoses including accidental overdoses at record levels in Australia, these medications are being increasingly used to treat CNCP despite limited evidence of their efficacy or safety.⁶

Concessional patients are prescribed a disproportionate amount of Schedule 8 opioids, especially for extended release products⁷ and the consumption of prescription opioids in regional areas is well above capital city levels, with the regional national average use of oxycodone almost double that of capital cities.⁸

A key factor in this prescribing pattern is the lack of access to multi-disciplinary pain management services due to cost or location.

Increasing access to alternative treatment options for those living with chronic pain are critical to reducing misuse of medications, along with a suite of regulatory reforms.

The Opioid Roundtable, convened by the Therapeutic Goods Administration (TGA) in May 2015 to improve patient safety and manage risk of PBS listed opioids involved 70 specialists, health professionals, pharmaceutical companies and policy makers. It concluded that while quality use of medicines will be driven by good regulation, a much wider range of service-wide health changes were also needed including:

- Recognising psychosocial factors that influence a patient's experience of pain, their chance of developing chronic pain and their risk of opioid misuse;
- that patients prescribed opioids should be managed under a comprehensive treatment plan that includes multi-modal strategies for pain management; and
- better system pathways and linkages between health professionals to facilitate this shared-care approach.⁹

Implementing and increasing access to this best practice model of care in all jurisdictions will require a range of policy approaches and investments which have not yet been made at a national level.

Australia is uniquely placed to advance a national response to pain as it was the first country in the world to advance a national framework for pain through the 2010 National Pain Strategy.

Developed by 200 stakeholders including health groups and consumers, the Strategy provides a blueprint for the treatment and management of acute, chronic and cancer pain and is an important resource for specialists, health care administrators and policy makers. It also identifies the key priorities for action including knowledge for consumers and health practitioners, access to multidisciplinary care and increased understandings of pain through research and information sharing.

Some states and territories have made commitments in line with the Strategy. Painaustralia urges national adoption of the Strategy by the Australian Government through the Council of Australian Governments (COAG) to ensure pain becomes a national health priority and the realisation of gains including the reduction in opioid misuse through prevention, community awareness and access to services.

The rollout of SafeScript and other monitoring systems are likely to reveal a range of complexities within the health system and across population groups that are misusing or at risk of misuse of pain medications or at risk of dependence and overuse. This data will be instrumental in informing policy priorities, the allocation of resources to programs, services and consumer awareness activities.

Understanding the intersection between regulatory reforms (including the rollout of real-time monitoring, the current review of opioid prescribing being carried out by the TGA and the recent up scheduling of codeine) and the development of national pain policy will be increasingly important in preventing misuse of prescription medications.

Recommendations to Victorian Government:

- Recognise the relationship between the misuse of pain medications and the need for greater access to best practice, multidisciplinary and holistic pain management services for chronic pain patients and the urgent need to implement a National Pain Strategy.
- Recognise the role of SafeScript in providing vital data and information to inform health policy, particularly as it relates to the delivery of pain services, early intervention and support.

Prescriber education

The reliance on opioid medications to treat chronic pain has a range of causes, including lack of education and awareness of pain management as described above and best practice prescribing practice. A crucial factor in the fall of opioid-related deaths in Tasmania following the implementation of its monitoring system is the quality of care patients received from their General Practitioners (GPs).¹⁰

SafeScript can play an important role by identifying patients at risk of drug misuse and unlikely to be accessing pain services, providing a gateway to a pain management pathway. It is also critical that health practitioners have solid awareness of health pathways options including the HealthPathways online portal provided through Primary Health Networks and used by clinicians at the point of care.

The training program identified in the RIS prior to implementation of SafeScript to be delivered through Primary Health Networks and NPS Medicine Wise must include modules on pain management education to increase awareness of pain, pain services and clinical pathways.

This is not currently reflected in the RIS.

The Faculty of Pain Medicine is well placed to assist with this, and there are other resources available through the Royal College of General Practice (RACGP), the NSW Agency for Clinical Innovation (ACI), the Pain Management Research Institute (PMRI) at University of Sydney and the Australian Pain Society (APS).

SafeScript can also identify concerns with prescribers and pharmacists that should also be directed towards mandatory education training on quality use of medicines, clinical guidelines and pain management options.

By making it mandatory, health practitioners who are geographically isolated, trained overseas or those that have been practising for some time can be incentivised and supported to receive training, which can also be a component of Continuing Professional Development (CPD) programs and mandatory for accreditation with the Medical and Pharmacy Boards.

Recommendations to Victorian Government:

- Include modules on health pathways and best practice pain management in training provided prior to the implementation of SafeScript.
- Recognise the role of SafeScript in identifying at risk health practitioners who require mandatory training in quality use of medicines and best practice pain medicine.

Consumer education

Knowledgeable, empowered and supported consumers are critical to address misuse of medications. These consumers understand the risks of medications, can seek out appropriate advice and treatment to better understand their pain take the first step for towards adopting self-management strategies that are proven to improve activity, reduce disability and keep pain to a minimum.¹¹

Painaustralia agrees with TGA that 'changes in prescriber behaviour and changes in community expectations about the use of opioids in management of CNCP will have greater impact on appropriate prescription and unsanctioned use of opioids although regulation has an important role to play.'¹²

Consumer literacy of the risks of pain medications and pain management options is low. As a community we rely on medications as 'quick fixes' to continue our daily lives, but this may mask more serious health issues. Painaustralia's recent Real Relief campaign was made available to 3.3 million Australians to raise awareness of why new access arrangement for codeine are necessary and alternative ways to manage their pain. Despite a survey of consumers showing over half supported the decision to upschedule the medication to prescription-only, many consumers conveyed their strong attachment to and reliance on codeine, a lack of knowledge about the risks of codeine and alternative pain treatment options.

SafeScript will be in the frontline of identifying patients misusing or at risk of misusing medications, including opioids and other pain medications.

Yet many people who live with chronic pain report stigma and misunderstanding in the community and amongst the medical profession, including their use of prescribed pain medications as part of their treatment. The use of language to describe opioid-associated behaviour includes misuse and 'doctor shopping' can contribute to the stigmatisation.¹³

It is critical SafeScript does not unintentionally or intentionally punish or stigmatise people with pain but rather take the opportunity to ensure they can access appropriate support systems and services, including information about pain conditions and best practice treatment and support options, consumer support services, public and privately funded pain clinics and online resources.

A range of quality resources are available on these options, but they should be collated and easily accessible for health practitioners as patients at risk are identified.

The Minister for Health has also recently announced \$20 million for Pain MedsCheck, a new trial program to be run in community pharmacies to support pharmacists to assist patients who are taking medication for chronic pain by evaluating a patient's medicine and the pain management program, ensuring it is supporting their clinical need and providing the best support.¹⁴

While this program is welcome, consumer education on both quality use of medicines and best practice pain management options will require resources and involvement of all spheres of the health sector.¹⁵

Recommendations to Victorian Government:

- Ensure SafeScript does not increase stigma experienced by people living with chronic pain and is accompanied by a strong consumer awareness campaign to increase understanding of pain, pain management and the quality use of medicines.

(2) SafeScript Design Options

In relation to the design options outlined in the RIS, Painaustralia:

- Supports the inclusion of codeine medications, due to the increase in codeine-related deaths¹⁶ and the need to understand how the medication is used in the community following the implementation of up scheduling from 1 February 2018.
- Notes that while people in aged care settings are deemed an appropriate exemption from SafeScript in the RIS, we urge all governments to redouble efforts to address poor quality pain management in these settings. This includes the urgent need to improve the prevention, treatment and management of pain across aged-care settings in general and to support quality use of pain medications.¹⁷ Drastically improving pain management practices in residential aged care settings is critical to reducing the misuse and the under or over-prescribing of pain medications, the prevalence of severe behaviours and improving quality of life for people living in these settings.¹⁸

Recommendations to Victorian Government:

- Understand and address widespread and poor pain management practices in residential aged care to improve quality use of medicines and quality of life in those facilities, noting they are deemed to be exempt from SafeScript in the RIS.

(3) Stakeholder engagement

Given the rollout of SafeScript is likely to precede the realisation of a national scheme, it is likely it will be a catalyst and potential model adopted by other jurisdictions or at the national level.

It is critical the design and implementation of the system is informed by the engagement and involvement of the broadest range of stakeholders including a range of medical and health groups and organisations that will be required to implement the system effectively, but also health consumers and their representative groups for whom this system directly affects.

This includes providing transparency that meets community expectations, while acknowledging commercial-in-confidence considerations, around the design and purchase of software and other design elements.

We note the important role of the SafeScript Expert Advisory Group but urge consideration of other consultation mechanisms to guide the implementation of the scheme.

This should include establishing a specific Consumer Advisory Group.

Painaustralia has a vast network of consumers that will be directly impacted by the rollout of this scheme and is well placed to coordinate and bring forward their views as they relate to the implementation and evaluation of SafeScript and other policy discussions.

Recommendations to Victorian Government:

- Engage and consult a wide range of stakeholders including consumers groups and national health groups in the design, delivery and evaluation of SafeScript.

Conclusion

While strongly welcoming the implementation of SafeScript, Painaustralia urges the Victorian Government to carefully consider the specific issues faced by people living with chronic pain in its policy development and regulatory settings.

This includes recognising the deep relationship between the misuse of pain medications and the need for much greater access to multi-disciplinary pain services, particularly for patients who have been prescribed opioid and other pain medications.

Painaustralia urges ongoing and strong engagement with a range of stakeholder groups in the implementation and evaluation of SafeScript.

We thank the Victorian Government for this consultation process and we stand ready to work with you and other key partners in ensuring the successful implementation and operation of SafeScript.

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