DRUGS, POISONS AND CONTROLLED SUBSTANCES AMENDMENT (REAL-TIME PRESCRIPTION MONITORING) REGULATIONS 2018

SUMMARY OF PUBLIC SUBMISSIONS ON THE REGULATORY IMPACT STATEMENT AND PROPOSED REGULATIONS

May 2018
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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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1. Introduction

The Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018 (the Regulations) support the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017 (the Act) by prescribing certain matters needed to implement an effective real-time prescription monitoring system (SafeScript), including:

- The medicines which will be monitored in SafeScript at commencement
- The entities that are required to ensure records are provided to SafeScript
- Details of what the prescription records must contain
- The clinical settings and circumstances where there are exceptions from mandatory use of SafeScript.

In February 2018, the Victorian Government released a Regulatory Impact Statement (RIS) and the proposed Regulations for mandatory public comment.

This report summarises the consultation process used for the making of the Regulations, the main themes arising from public consultations and the department’s response to the submissions.


Appendix 2 contains the list of stakeholders that were notified of the release of the Regulatory Impact Statement and proposed Regulations and those that provided written submissions.

2. Consultation process

Consultation for preparing the RIS and proposed Regulations

Stakeholder consultation for preparing the RIS and proposed Regulations followed on from the consultations for the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill 2017 which was introduced into the Victorian Parliament in August 2017.

An advisory group was established in 2016 to advise on matters relevant to the implementation of SafeScript in Victoria. The SafeScript External Advisory Group includes representation across the major medical and pharmacy organisations, as well as other key stakeholder groups, namely:

- Australian Medical Association Victoria
- Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists
- Medical Software Industry Association
- Pharmaceutical Society of Australia Victorian Branch
- Pharmacy Guild of Australia Victoria Branch
- Royal Australasian College of Physicians
- Royal Australian College of General Practitioners Victoria
- Rural Doctors Association of Victoria
- ScriptWise
- Victorian Aboriginal Community Controlled Health Organisation
Advice from the SafeScript External Advisory Group has informed several key implementation aspects of the SafeScript framework, including those matters which require regulations to be made, namely the scope of medicines to be monitored, mandating the use of SafeScript and the exceptions from mandatory use.

The SafeScript External Advisory Group considered the findings of an Austin Health literature review commissioned by the Victorian Government in March 2017. The literature review analysed a number of data sources, including overdose deaths, poisons information centre data, ambulance callout data and trends of use and misuse to determine which medicines were causing the greatest harm in the community.

Recommendations made by the SafeScript External Advisory Group on which medicines should be monitored in SafeScript were accepted by the Victorian Government and included in the proposed Regulations.

Consultation on the RIS and proposed Regulations

The RIS was assessed as suitable for public consultation by the Office of the Commissioner for Better Regulation and was released together with the settled proposed Regulations and the draft Human Rights certificate, for public consultation on 8 February 2018 until 7 March 2018.

A Notice of Preparation of Regulatory Impact Statement and proposed Regulations was published in the Victorian Government Gazette (Number G 6), the Herald-Sun newspaper and The Age newspaper on 8 February 2018.

Forty-one organisations were informed in writing of the release of the Regulatory Impact Statement and proposed Regulations and were invited to make a submission (refer to Appendix 2). Messaging through the Victorian Government’s social media accounts also invited public submissions.

Twenty-seven written submissions were received. The department wishes to thank those who have contributed their time and expertise to the consultation process to date.

Submissions were received from:

- Medical organisations (3 submissions)
- Nursing organisations (2 submissions)
- Pharmacy organisations (3 submissions)
- Alcohol and other drug organisations (5 submissions)
- Consumer organisations (1 submission)
- Government/statutory organisations (2 submissions)
- Other organisations (4 submissions)
- Individual health practitioners (3 submissions)
- Individual consumers (4 submissions).
3. Key themes raised in submissions

The submissions received on the Regulatory Impact Statement and proposed Regulations were strongly supportive of the implementation of SafeScript. Submissions commended the Victorian Government on the extensive consultation with clinicians and other key stakeholders on important aspects of SafeScript, and encouraged the Government to continue its engagement with stakeholders throughout the implementation of SafeScript.

The main themes raised through the submissions are discussed below.

**Medicines to be included in SafeScript**

Submissions from the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, Australian Government Department of Health (from the Secretary on behalf of the Therapeutic Goods Administration), Australian Medical Association Victoria, Harm Reduction Victoria, Pharmaceutical Society of Australia Victorian Branch, Pharmacy Guild of Australia Victorian Branch, Royal Australian College of General Practitioners Victoria and Western Victoria Primary Health Network recommended that Schedule 4 codeine products be included in SafeScript from commencement. Submissions raised that monitoring of codeine was required from the start to prevent the possibility that the prescribing of opioid medicines that are included in SafeScript will shift to codeine, should it not be monitored.

In April 2017, the SafeScript External Advisory Group recommended that all Schedule 8 medicines, all benzodiazepines, z-drugs and quetiapine be included in SafeScript at the start of implementation. The advisory group also recommended that Schedule 4 codeine products be included at a later stage to allow clinicians time to adjust to the rescheduling of over-the-counter codeine in February 2018 to prescription only. These recommendations were accepted by the Victorian Government and included in the proposed Regulations.

Following the rescheduling of over-the-counter codeine in February 2018 and on the basis of the strong feedback received in the submissions to bring forward the monitoring of codeine, in April 2018 the advisory group revisited its advice on the timing of when codeine should be included in SafeScript.

There was unanimous support from the advisory group for codeine to be included in SafeScript from the start of implementation and mandatory checking of codeine prescriptions from April 2020. The advisory group advised that the rescheduling of codeine has not resulted in the major flow-on impacts to healthcare or service providers as had been anticipated, and consequently, the inclusion of codeine need no longer be delayed. The Victorian Government has accepted this recommendation from the advisory group and the Regulations will be amended to reflect this.

Submissions from the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists and the Therapeutic Goods Administration (through the Australian Government Department of Health) recommended that tramadol be monitored. A submission from the Royal Australian College of General Practitioners Victoria recommended that medicinal cannabis be monitored. A submission from the State Coroner of Victoria supported including all prescription medicines.

SafeScript is not intended to monitor all prescription medicines, but rather to provide clinicians with pertinent information on the supply of high-risk medicines. SafeScript is designed to not overwhelm a clinician with information, but enable clinicians to make safe and timely decisions based on the most critical data for the most risky medicines.

With regard to the medicines that have not been included at the start of implementation, the Regulations enable additional medicines to be included in SafeScript in the future should they emerge as causing significant risk of harm to the community.
Exception from mandatory use when treating palliative care patients

When use of SafeScript becomes mandatory, the Regulations provide for an exception from the requirement to check SafeScript before prescribing or dispensing a monitored medicine when treating palliative care patients, provided the patient is not a drug-dependent person.

The proposal not to include drug-dependent persons within the palliative care exemption was in line with the current additional requirements set out in the Drugs, Poisons and Controlled Substances Act 1981 when treating drug-dependent persons.

Submissions from the Australian Medical Association Victoria, Harm Reduction Victoria, Pharmaceutical Society of Australia Victorian Branch, Pharmacy Guild of Australia Victorian Branch and Victorian Alcohol and Drug Association recommended that the condition in which the exception applied only to non-drug dependent patients be removed. Submissions raised that establishing whether a patient is drug-dependent may be difficult to ascertain in practice and time consuming. Submissions also raised that this may create a potential barrier for palliative care patients at a stage where the focus for clinicians is on providing compassionate care and improving quality of life.

As a consequence of this feedback, the Regulations will be amended to provide for an exception from mandatory use of SafeScript when treating any palliative care patient.

Extending membership of the SafeScript External Advisory Group

A joint submission from the Society of Hospital Pharmacists of Australia Victorian Branch and Victorian Therapeutics Advisory Group, and submissions from Pain Australia and two individual psychiatrists recommended that the SafeScript External Advisory Group include a wider group of stakeholders and greater consumer representation as implementation approaches to ensure that SafeScript is implemented successfully in all practice settings.

Membership of the SafeScript External Advisory Group was expanded to include:

- Society of Hospital Pharmacists of Australia Victorian Branch
- Royal Australian and New Zealand College of Psychiatrists Victorian Branch
- extra consumers.

Impact on support services and alcohol and other drug treatment services

Submissions from the Alcohol and Drug Foundation, Australasian Professional Society on Alcohol and Other Drugs, Drug and Alcohol Nurses of Australasia, Harm Reduction Victoria, Pain Australia, Royal Australian and New Zealand College of Psychiatrists Victorian Branch, State Coroner of Victoria, Victorian Alcohol and Drug Association, Victorian Council of Social Service, Windana Drug and Alcohol Recovery and Western Victoria Primary Health Network raised some concern about the impact on support services including pain management, mental health, opioid replacement therapy, or alcohol and other drug (AOD) treatment services when SafeScript is implemented.

The SafeScript project continues to progress the development of key supporting workforce and other initiatives including:

- Comprehensive state-wide training for clinicians with a focus on ensuring clinicians are able to respond to patient needs in the primary care setting
- Establishing a network of General Practitioners to provide peer-to-peer support in managing patients with more complex needs
- Minor enhancements to the AOD treatment system, including augmenting counselling and support services for people with prescription medicine dependency, including benzodiazepines
• A mainstream media public awareness campaign to raise community awareness of the harms from prescription medicines.

Given that SafeScript will be introduced state-wide following an initial phase and evaluation, and also given that there will be an 18-month non-mandatory period to allow SafeScript to be embedded into clinical practice and allow services time to adapt to the system, it is not likely that services will experience an immediate or sudden influx of new clients.

Importantly, the non-mandatory period will provide both the department and our training provider with early insights on the scale of patients who may need support or treatment for prescription medicine dependency. Our training and other support packages can be adjusted accordingly.

It is important to acknowledge that SafeScript is part of a whole of Victorian Government response to reducing the harms of substance use. The Victorian Government has made significant new investment in the AOD sector through initiatives such as the Drug Rehabilitation Plan, which includes the expansion of training to boost the AOD workforce and investment in 100 additional residential rehabilitation beds. As these services are not drug specific, they will also be available to people with prescription medicine dependency.

Further to this, the 2018/2019 Victorian Budget will provide a record investment of $705 million for mental illness and addiction support, including:

• $100.5 million to fund six new emergency department crisis hubs at Monash Medical Centre, St Vincent’s, Geelong, Royal Melbourne, Sunshine and Frankston Hospital emergency departments
• $40.6 million to fund three new residential drug rehabilitation treatment facilities, each with 30 beds, to be built in the Barwon, Gippsland and Hume regions
• $28.6 million to provide more treatment options and improve clinical care in six Prevention and Recovery Care (PARC) units and $11.9 million to build a 20-bed PARC facility for young people across Melbourne.

These additional new services will also be available to patients who might be identified through SafeScript as developing signs of prescription medicine dependency and require further support.

The potential for SafeScript to contribute to stigma

Submissions from the Alcohol and Drug Foundation, Australasian Professional Society on Alcohol and Other Drugs, Harm Reduction Victoria, Pain Australia, Victorian Alcohol and Drug Association and Windana Drug and Alcohol Recovery raised the importance of ensuring that SafeScript does not cause stigma for patients who take high-risk medicines or those who may need support for prescription medicine dependency.

The department agrees that critical to the success of SafeScript is that it does not contribute to stigma and that vulnerable patients who may need support are not abandoned by their clinicians.

The training that will be provided to clinicians will include a focus on the use of non-stigmatising language and a patient-centred approach to managing patients who are developing signs of prescription medicine dependency. The training will provide advice on how to engage with patients in a respectful and empathetic manner when discussing such sensitive matters.

The Public Awareness Campaign that will be launched leading up to the implementation of SafeScript will raise awareness of the growing concerns of prescription medicine harms and empathy for those affected without creating stigma.
4. Other matters raised in submissions

18 month non-mandatory period

Three submissions (two alcohol and drug organisations, one not-for-profit organisation) raised that introducing SafeScript with an 18 month non-mandatory may be too long and consideration should be given to shortening this period. Submissions raised that more deaths during this period could be prevented if clinicians were required to check SafeScript before prescribing or dispensing a high-risk medicine.

The 18 month non-mandatory period has been included to allow time for health practitioners to familiarise themselves with the system and incorporate it into their clinical practice. The duration of this period is appropriate as major changes to clinical practice require sufficient time to be fully embedded and adopted by all clinicians.

A number of measures will be implemented to promote high uptake of SafeScript during the non-mandatory period. These include:

- Providing an integrated workflow to facilitate access to SafeScript. This was a key reason why Victoria decided to develop bespoke software and not implement the original Commonwealth software which did not provide this critical feature.
- Reduced Schedule 8 permit and notification requirements for clinicians who use SafeScript. Streamlining the permit and notification requirements was extensively researched and consulted on with the SafeScript External Advisory Group.
- Communications and training to inform how using SafeScript will assist with meeting existing professional and regulatory obligations in providing safe and appropriate clinical care.
- A behavioural insights approach. Analysing trends on the locations or clinical settings where SafeScript is being used will inform the areas in which further communications and education activities are necessary to encourage increased use.

Integrated clinician workflow

Four submissions (two medical organisations, one pharmacy organisation, one medical indemnity organisation) raised the importance that SafeScript is integrated with existing clinical practice systems to minimise impact on clinicians, particularly when the use of SafeScript becomes mandatory in April 2020.

Integration with existing workflows was a key reason why Victoria proceeded with developing purpose-built software in order to meet this critical requirement for clinicians.

The design of SafeScript leverages infrastructure developed by the Prescription Exchange Services, which are electronic prescription repositories that support national e-health initiatives, including the electronic transfer of prescriptions.

SafeScript will have minimal interruption to clinical workflow so that patient care remains the key focus. SafeScript will provide prescribers and pharmacists with pop-up notifications in real-time to provide information on whether records relating to a patient exists within SafeScript and requires further investigation, and the patient history can be accessed through an integrated link contained in the pop-up notification. This feature will be available from the start of implementation with any practice system connected to a Prescription Exchange Service.

Two submissions (two medical organisations) requested that support be considered for prescribers who do not use electronic prescribing software. While SafeScript has been designed to integrate with clinical
workflows for clinicians using prescribing software, access will still be available at all times for prescribers who write paper prescriptions via a secure web portal.

Clinicians who have registered to use SafeScript but do not have access to the internet during a patient consultation may contact the department to enquire about a patient’s history in SafeScript during business hours. However, as additional authentication will be required to verify the identity of the caller, this will not be as efficient as directly accessing SafeScript to view a patient’s history.

Cross-border issues
Six submissions (two alcohol and drug organisations, one medical organisation, one consumer organisation, one medical indemnity organisation, one individual psychiatrist) noted the importance that SafeScript needs to be part of a national system in order to reduce the risk of cross-border issues.

Victoria absolutely agrees that a national data sharing arrangement is a must. Victoria continues to work with jurisdictions and the Commonwealth towards the implementation of national real-time prescription monitoring. In April 2018, the Council of Australian Governments Health Council agreed to progress with an approach based on SafeScript’s design principles. This will assist in ensuring that all jurisdictional systems will be interoperable, data can be shared between all jurisdictions, and clinicians have a system that is easier to use.

The Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017 will enable Victoria to enter agreements or memoranda of understanding with any jurisdiction or the Commonwealth, to facilitate the exchange of information between jurisdictions for the purposes of a national system.

While Victoria will be implementing SafeScript ahead of a national system, the Regulations will enable Victoria to collect records of prescriptions that have been written or dispensed interstate for a Victorian patient. While ultimately a national system is the goal, this intermediate step will partially address cross-border issues while other jurisdictions progress with implementation of real-time prescription monitoring.

Access to SafeScript in hospitals
Four submissions (two alcohol and drug organisations, one medical organisation, one hospital organisation) raised matters relating to the use of SafeScript in hospitals, including concern that emergency departments would not have access to SafeScript.

The department agrees that there is a need for access to SafeScript in certain hospital settings. SafeScript will be available to prescribers and pharmacists in all clinical settings, including hospitals.

When SafeScript becomes mandatory, hospital clinicians will be required to check SafeScript before prescribing or supplying a medicine that is intended for use outside of a hospital setting, for example, when supplying medicines to a patient on discharge or as an outpatient. The proposed Regulations provide for exceptions from the requirement to check SafeScript for hospital in-patient settings and in emergency departments where medicines are administered under supervision.

Some submissions may have assumed that hospitals will not have access to SafeScript at all. While the Regulations provide for exceptions from mandatory use, hospital clinicians will still be provided with access to SafeScript to check patient records in any hospital setting in order to inform clinical decisions.

Penalties for practitioners who do not check SafeScript
While penalties are not specified in the Regulations, two submissions (one medical organisation, one medical indemnity organisation) raised concerns that the penalty of 100 penalty units for practitioners who fail to check SafeScript when prescribing or dispensing a monitored medicine is excessive.
This mischaracterisation of how penalties might be imposed on clinicians has also appeared in some online medical publications recently.

The *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017* does indeed specify penalties that can be imposed on clinicians who do not take all reasonable steps to check SafeScript when prescribing or dispensing a high-risk medicine. The phrase “take all reasonable steps” is important to note and is a phrase used throughout the drugs and poisons legislative framework.

These penalties of 100 penalty units are identical to the existing penalties in drugs and poisons legislation for failing to apply for a Schedule 8 permit. The same level of penalties have been in place under drugs and poisons legislation in Victoria since the early 1960s.

While the Act has provisions to prosecute for failure to comply with these requirements, non-compliant activities will be assessed within a risk-based model. This will enable allocation of department resources and enforcement decisions to be directed toward non-compliant activities that pose the most significant risks of harm to patients and practitioners who have repeatedly failed to comply with SafeScript requirements.

The department will utilise a range of compliance tools, including education and counselling, to assist practitioners meet their regulatory obligations for SafeScript, and will take in account the individual circumstances before any consideration is made on a decision to initiate prosecution.

**Access to SafeScript for other health practitioners**

Two submissions (one nursing organisation, one alcohol and drug organisation) asked that consideration be given to provide health practitioners, including alcohol and drug nurses or rural and isolated practice endorsed registered nurses (RIPERNs) with access to SafeScript.

SafeScript is a clinical support tool so that clinicians involved in the prescribing or supplying of high-risk medicines have full information on previous supply at the point of consultation.

Medical practitioners, nurse practitioners and pharmacists will have access to SafeScript when it commences, given the prescribing and supplying of high-risk medicines for treatment of chronic conditions in the community setting predominantly involve these practitioners.

While there are nurses and midwives who are endorsed to prescribe or supply certain high-risk medicines, this is restricted to limited acute care circumstances.

The *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017* will enable other health practitioners to be given access to SafeScript in the future should their scope of practice change to include prescribing or supplying of these high-risk medicines for chronic conditions.

**Economic analysis underestimating costs**

Three submissions (one alcohol and drug organisation, one pharmacy organisation, one not-for-profit organisation) suggested that the economic analysis in the Regulatory Impact Statement (RIS) had underestimated the cost for clinicians to comply with the Regulations as well as the impact that SafeScript will have on the health and AOD sectors.

As with all cost-benefit modelling in regulatory impact statements, best data available was used and some assumptions were necessary in order to estimate the costs. A conservative approach was taken to ensure the benefits of the implementation of SafeScript were not overestimated. A sensitivity analysis was also performed on the cost variables to accommodate a level of uncertainty in estimating the costs.

Input was also provided by the SafeScript External Advisory Group during the development of the RIS in late 2017. The Deloitte Access Economics team which the department engaged to undertake the cost-
benefit analysis had considerable experience in conducting such analyses in health economics. The validity of the economic modelling was reviewed by the Office of the Commissioner for Better Regulation before being released for public comment.
Appendix 1: Notices published

Preparation of Regulatory Impact Statement

Subordinate Legislation Act 1994
NOTICE OF PREPARATION OF REGULATORY IMPACT STATEMENT
Proposed Drugs, Poisons and Controlled Substances Amendment
(Real-time Prescription Monitoring) Regulations 2018

Notice is given in accordance with section 11 of the Subordinate Legislation Act 1994 that a Regulatory Impact Statement (RIS) has been prepared in relation to the proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018 (the proposed Regulations).

The proposed Regulations, to be made under the Drugs, Poisons and Controlled Substances Act 1981 (the Act) (as amended by the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017) prescribe certain matters needed to implement parts of the Act concerning the implementation of real-time prescription monitoring.

The proposed Regulations support the Act in promoting the safe supply and reducing the risk of harm of prescription medicines through the implementation of a real-time prescription monitoring system (referred to in the proposed Regulations as a monitored poisons database). The proposed Regulations will:
(a) prescribe entities required to provide information to the monitored poisons database;
(b) prescribe poisons which are to be monitored on the monitored poisons database;
(c) prescribe exceptions to the requirement to check the monitored poisons database;
(d) prescribe the content of records to be provided to the monitored poisons database; and
(e) make consequential amendments.

The RIS presents the potential cost to industry of implementing the proposed Regulations, the expected financial and social benefits and alternative regulatory approaches for the implementation of real-time prescription monitoring.

Copies of the RIS and the proposed Regulations may be obtained from the Department of Health and Human Services website at https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript

Public comments are invited on the RIS and the proposed Regulations. All comments must be in writing and should be marked ‘RTPM Regulations Comments’.

Comments must be received no later than 5 pm on Wednesday 7 March 2018, via email to: safescript@dhs.vic.gov.au; or by mail to: Project Director, Real-Time Prescription Monitoring Implementation, Department of Health and Human Services, GPO Box 4057, Melbourne, Victoria 3001.

All comments and submissions will be treated as public documents, unless the person making the comment or submission requests that it not be publicly available.

HON. JILL HENNESSY MP
Minister for Health
Appendix 2: Consultation for the RIS

Stakeholders notified and submissions received

The following table lists the organisations that were informed of the release of the RIS and the proposed Regulations, and the organisations that provided a submission.

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<th>Notified of the RIS</th>
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<td>Australian Salaried Medical Officers’ Federation</td>
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<tr>
<td>Department of Health (Queensland)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Department of Health and Ageing (SA)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Department of Health and Human Services</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>(Tasmania)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Department of Health (WA)</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

**Individuals**

<table>
<thead>
<tr>
<th>Individual</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>One general practitioner</td>
<td>✓ x 1</td>
</tr>
<tr>
<td>Two psychiatrists</td>
<td>✓ x 2</td>
</tr>
<tr>
<td>Four consumers</td>
<td>✓ x 4</td>
</tr>
</tbody>
</table>