Regulatory Impact Statement – Schedule 5 & Schedule 6 of the Drugs, Poisons and Controlled Substances Regulations 2017

Victorian Department of Health

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Contents

Glossary

Abbreviation	Stands for
ABS	Australian Bureau of Statistics
AOD	Alcohol and Other Drugs
BCR	Benefit cost ratio
CBA	Cost Benefit Analysis
the Act	Drugs, Poisons and Controlled Substances Act 1981
the Regulations	Drugs, Poisons and Controlled Substances Regulations 2017
DH	Department of Health (Victoria)
NPV	Net present value
PBS	Pharmaceutical Benefits Scheme
PV	Present value terms
RIS	Regulatory Impact Statement
RTPM system	Real Time Prescription Monitoring system
TGA	Therapeutic Goods Administration
2018 RIS	*Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018*

Foreword

This Regulatory Impact Statement (RIS) has been prepared with respect to proposed amendments to the Drugs, Poisons and Controlled Substances Regulations 2017 (The Act) made under the *Drugs, Poisons and Controlled Substances Act 1981* (The Regulations).

The RIS should be read in conjunction with the proposed regulations, which are provided as a separate document.

This RIS sets out the objectives of the proposed regulations, explains their effect and assesses the nature and scope of the problem that the proposed regulations seek to address. It also sets out the likely impacts (costs and benefits) and discusses alternatives.

How to respond to the proposed Regulations

Interested parties and members of the public are invited to make submissions responding to the RIS or the proposed regulations.

The closing date for submissions is Friday 31 March 2023.

Comments may be provided via email to the following email address: dpcs@health.vic.gov.au

Hard copy submissions will also be accepted and should be addressed to:

Medicines and Poisons Regulation

Department of Health

GPO Box 4057 Melbourne VIC 3001

For further assistance about the public comment process, or to obtain copies of the RIS and proposed Regulations, please email dpcs@health.vic.gov.au

Executive summary

Purpose of this RIS

The purpose of this RIS is to evaluate options for the inclusion of the medicines pregabalin, gabapentin and tramadol in the medicines monitored by Victoria's Real-time Prescription Monitoring (RTPM) system, SafeScript.

Pregabalin and gabapentin are classed as gabapentinoids and used in the treatment of neuropathic pain (pain caused by an abnormality of, or damage to, the nerves) and epilepsy.[1] Tramadol is an opioid-like analgesic used for short-term relief of moderate to severe pain.

The three medicines are included in Schedule 4 (Prescription Only Medicine) of the national Poisons Standard. The Poisons Standard is a legislative instrument prepared under the *Therapeutic Goods Act 1989 (Cwlth)*. Schedule 4 poisons can only be obtained from a registered health practitioner who is authorised to sell or supply, including to issue a prescription for, a Schedule 4 poison under the *Drugs, Poisons and Controlled Substances Act 1981* (the Act).

Including new medicines in SafeScript will require an amendment to Schedule 5 – Monitored poisons and Schedule 6 – Monitored supply poisons of the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations). Schedule 5 enables the collection of the medicines into SafeScript whereas Schedule 6 mandates the medicines that prescribers and pharmacists need to check in SafeScript before supplying.

Under section 7 of the *Subordinate Legislation Act 1994*, a RIS is required to be prepared for proposed regulations[2]. The responsible Minister must ensure a RIS is prepared for public consultation.

DH has engaged Sapere Research Group to prepare this RIS in accordance with BRV's Victorian Guide to Regulation[3] and the *Subordinate Legislation Act 1994*.

The analysis in this RIS relates to the inclusion of additional medicines to be monitored in Victoria's RTPM system SafeScript. It is noted that a RIS was produced in 2018 to assess options for establishing SafeScript, including the medicines to be monitored (referred to in this document as the 2018 RIS). Th 2018 RIS is available on the BRV website.[4]

[1] Australian Government Therapeutic Goods Administration, https://www.tga.gov.au/news/safety-alerts/pregabalin-and-gabapentin.
[2] Unless there is an exemption under section 8 of the Subordinate Legislation Act.
[3] Office of the Commissioner for Better Regulation, 2016, Victorian Guide to Regulation: A handbook for policy makers in Victoria, Department of Treasury and Finance, Melbourne.
[4] Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018, available at https://www.vic.gov.au/regulatory-impact-statements-2018.

Problem analysis

Pregabalin, gabapentin and tramadol have contributed to overdose deaths in Victoria, particularly pregabalin in the last five years, but none is monitored in SafeScript. Table 1 shows annual frequency of overdose deaths by contributing drug type plus alcohol and illegal drugs[5].

Table 1 Annual frequency of overdose deaths where pregabalin and tramadol contributed plus major contributing pharmaceutical drug groups plus alcohol and illegal drugs, Victoria 2017-2021.

	2017	2018	2019	2020	2021
Benzodiazepines	303	304	285	284	266
Illegal drugs	267	260	274	276	260
Pharmaceutical opioids					
Tramadol	*32*	*35*	*37*	*28*	*20*
Other pharmaceutical opioids	166	172	170	164	162
Antidepressants	196	196	170	181	159
Alcohol	151	161	145	155	147
Antipsychotics	136	109	103	113	99
Anticonvulsants					
Pregabalin	*52*	*69*	*66*	*69*	*65*
Other anticonvulsants	23	18	19	23	20
Non-benzo anxiolytics	56	47	54	51	46
Non-opioid analgesics	38	40	50	37	21
Total	**1,420**	**1,411**	**1,373**	**1,381**	**1,265**

Source: Coroners Court of Victoria, Table 8, Victorian overdose deaths, 2012-2021.[6]

Summary of options considered

This RIS analyses three options:

- **Base Case**: no change to the medicines monitored in SafeScript
- **Option 1**: add pregabalin and gabapentin to the medicines monitored in SafeScript
- **Option 2**: add pregabalin, gabapentin and tramadol to the medicines monitored in SafeScript (Option 1 plus tramadol).

The impacts of Options 1 and 2 are assessed against the base case.

[5] Gabapentin is not included in the Coroners Court data set. Pregabalin and gabapentin are discussed together because they are in the same class, have same or similar risk profile, and would be substituted for each other in prescribing practices.

[6] Note the total calculated in this table is different to the total calculated in the source document.

Given the well-established regulatory framework for regulation of prescription medicines at both a Commonwealth and state and territory level, and Victoria's established RTPM system, SafeScript, the focus of this RIS is limited to considering pregabalin, gabapentin and tramadol for inclusion in SafeScript and does not consider options outside of this scope.

Options analysis

A cost benefit analysis (CBA) is used in this RIS to assess the real costs and benefits of each of the options incrementally to the base case. Where possible, costs and benefits that are quantified are assessed in an economic model by estimating each cost and benefit over a 10-year timeframe commencing 2022-23. The aggregated costs and benefits are expressed using two key metrics: Net Present Value (NPV) and Benefit-Cost Ratio (BCR).

The costs and benefits quantified in this analysis are outlined in Table 2 and Table 3 below. Costs and benefits that cannot be quantified are discussed qualitatively.

Table 2 Description of costs

Costs	Description of cost	Stakeholder
Software amendment costs	The once-off cost incurred by DH to amend the SafeScript software to accommodate the proposed new medicines, excluding all other government implementation costs.	Government
Stakeholder communication costs	The once-off stakeholder communication cost to government about the changes	Government
Extra system maintenance	Any additional ongoing costs incurred by DH to maintain SafeScript as a result of including the proposed new medicines.	Government
Government monitoring and enforcement costs	The ongoing costs incurred by DH to monitor and enforce compliance with the proposed regulations.	Government
Cost of learning about change for prescribers and pharmacists	The once-off cost for prescribers and pharmacists to learn about the changes to SafeScript. This will include learning about the addition of the proposed new medicines to SafeScript and relevant information about the new medicines that have been added.	Industry
Compliance costs	The ongoing costs of time to prescribers to check SafeScript prior to issuing a prescription for or supplying any of the proposed new medicines and the cost to pharmacists to check SafeScript prior to dispensing any of the new medicines.	Industry

Costs	Description of cost	Stakeholder
Extra time for patients to obtain prescriptions	The ongoing costs of time to people waiting for a prescription to be checked by a medical practitioner or pharmacist.	Victorian community
Treatment costs (for treatment of dependency)	The costs incurred to treat those identified via the SafeScript check as being at risk of harm, either through Alcohol and Other Drugs (AOD) programs or through appropriate primary care. This is an intervention in addition to the decision made by a medical practitioner not to issue a prescription.	Victorian community and/or government (depending on whether privately or publicly funded)

Table 3 Description of benefits

Benefits	Description of benefit	Stakeholder
Lives saved by SafeScript	Value of lives saved by SafeScript. Value can be quantified by multiplying the number of avoided deaths by the value of a statistical life.	Victorian community
Reduced hospitalisations	Value of saved resources by reducing the number of patients that are admitted to hospital.	Government/Victorian community
Avoided emergency department presentations	Value of saved resources by reducing the number of patients that present to emergency departments.	Government/Victorian community
Avoided Pharmaceutical Benefits Scheme (PBS) costs[7]	Value of PBS subsidy for prescriptions not supplied.	Commonwealth government

Table 4 presents the results of the CBA with both Option 1 and 2 indicating positive NPVs and BCRs. Option 2 (which includes pregabalin, gabapentin and tramadol in SafeScript) is the overall preferred option with the highest NPV of $100.6 million over 10 years and BCR of 1.46 relative to the Base Case. Option 1 (which includes pregabalin and gabapentin in SafeScript) is also preferred to the Base Case, with a positive NPV of $37.7 million over 10 years and BCR of 1.24 relative to the Base Case.

[7] As these benefits accrue to the Commonwealth PBS and are unlikely to have direct effects on Victorians they are described and quantified but not considered in the total quantified cost estimate.

These CBA results only include impacts that are quantified. There is a range of impacts likely to arise from the proposed changes that have not been quantified but will increase the net benefits achieved under both Options 1 and 2. These include avoided doctor consultations, avoided ambulance trips, improved quality of life, avoided workplace costs and avoided social costs for those living with a person affected by misuse of the medicines being proposed.

Table 4 Cost-benefit analysis results (NPV and BCR)

Costs	Option 1	Option 2 (preferred option)
Once-off software amendment costs	$149	$149
Stakeholder communication costs	$4,013	$4,013
Once-off learning - prescribers and pharmacists	$986,790	$986,790
Government monitoring and enforcement costs	$47,809	$71,714
Compliance costs for prescribers and pharmacists	$73,388,485	$83,203,476
Extra time for patients to obtain prescriptions	$37,033,069	$40,442,040
Treatment costs	$43,459,648	$91,899,924
Total costs	**$154,919,963**	**$216,608,106**
Benefits[8]		
Lives saved by SafeScript	$187,836,160	$309,362,084
Avoided emergency department presentations	$3,558,094	$5,860,104
Reduced hospitalisations	$1,228,430	$2,023,197
Total benefits	**$192,622,684**	**$317,245,386**
NPV	**$37,702,720**	**$100,637,279**
BCR	**1.24**	**1.46**

The key assumptions estimated in this analysis, which underpin the largest cost and benefit drivers, are:

- Compliance costs:
  - 1 minute for a prescriber or pharmacist to check SafeScript (note pharmacists need to check more prescriptions than prescribers because of the need to check repeat prescriptions).
- Extra time for patients to obtain prescriptions:
  - 1 minute for a patient to wait for each prescription to be checked by the prescriber and the pharmacist.
- Treatment costs (for treatment of dependency)[9]:

[8] Does not include avoided PBS costs as these benefits accrue to the Commonwealth PBS and unlikely to have direct effects on Victorians and are therefore not considered in the total quantified cost estimate.

[9] As noted in Table 2, this is the cost incurred to treat those identified via the SafeScript check as being at risk of harm, either through AOD programs or through appropriate primary care. This is an intervention in addition to the decision made by a medical practitioner not to issue a prescription.

- 80% of patients requesting inappropriate prescriptions receive treatment. The other 20% do not receive any treatment.
- Of the 80% who receive treatment, 25% people are treated through an AOD program (higher cost intervention). The other 75% are treated through appropriate primary care e.g. provided by their general practitioner (lower cost intervention).

- Benefit of lives saved by SafeScript:
  - The largest benefit by far in the CBA is the benefit of lives saved by SafeScript. It is assumed that the inclusion of the medicines in SafeScript reduces deaths by 5% under Options 1 and 2 compared to the Base Case. This assumption takes into account the Tasmanian evidence from the introduction of an RPTM system, the US evidence and the experience under SafeScript since 2018[10]. Based on this assumption there will be 77 avoided deaths due to pregabalin and gabapentin over the period 2023 to 2032, and 47 avoided deaths due to tramadol. The benefit is estimated by multiplying avoided deaths by a statistical value of life of $4.96 million (present value FY23).
  - Sensitivity testing was undertaken for the assumption of avoided deaths because despite an evidence based central estimate of 5%, this benefit remains a key driver of results. The percentage of forecast deaths avoided is tested at high 7% and low 3% compared to the central assumption of 5%[11]. For Option 1 an increase in this assumption from 5% to 7% increases the BCR from the central estimate of 1.24 to 1.74. For Option 2 an increase in this assumption to 7% increases the BCR from the central estimate of 1.46 to 2.05. A reduction in this assumption to 3% will result in a negative BCR of 0.75 for Option 1 and 0.88 for Option 2, although based on the evidence available this is considered unlikely to occur.

These assumptions are discussed in detail in Chapter 4 of this RIS.

Small business and competition impacts

As nearly all GP clinics (97 per cent) and a majority of pharmacies (56 per cent) in Victoria are considered small businesses, much of the impact of the proposed change to the Regulations will be borne by small businesses (defined by the ATO as those with an annual turnover of less than $2 million).[12]

General practitioners, nurse practitioners and pharmacists in clinics and community pharmacies are already required to check SafeScript and therefore have well established IT systems and processes in place. There will be a small cost (estimated to be 30 minutes of time per practitioner and pharmacist) to learn about the changes.

As every general practitioner, nurse practitioner and pharmacist will need to learn about the new requirement and then do checks as needed for their patients, this is not expected to disproportionately impact small businesses.

[10] Noting these examples relate to a broader range of medicines included in the RPTM systems than just pregabalin, gabapentin and tramadol.
[11] Note the lower and upper bound estimates used for sensitivity testing are not evidence based and are used to illustrate the sensitivity of results to a change in the assumption.
[12] Australian Bureau of Statistics, *8165.0 Counts of Australian Businesses, including Entries and Exits*, June 2017 to June 2021, Businesses by Main State by Industry Class by Turnover Size Ranges, June 2021 (a) (b), (Data Cube 3).

It is not expected that there will be any material competition impacts as a result of adding the three additional medicines to SafeScript.

Implementation

Because the proposed change only involves adding a small number of medicines to Schedule 5 and 6 in the existing Regulations, the work required to implement the changes is expected to be minimal.

DH will be responsible for overseeing all changes brought about by the implementation of the proposed changes and for administering and monitoring health professional compliance to ensure they meet their legal obligations in using SafeScript appropriately.

DH are responsible for implementing the SafeScript RTPM system and are currently responsible for administration of SafeScript. They have a responsibility to identify and address industry compliance. DH have the regulatory understanding and technical skills to undertake implementation of any changes and ongoing administration of SafeScript using existing policies and processes.

The main steps in implementation are:

- Add medicines to SafeScript RTPM system
- Communicate with practitioners and pharmacists to inform them that new medicines have been added
- Communicate with key stakeholders and general public to inform them that new medicines have been added
- Provide learning and training materials for practitioners and pharmacists.

Evaluation

This RIS proposes that the evaluation strategy for the proposed new medicines comprises the following two elements which are in line with the evaluation strategy for SafeScript as proposed in the 2018 RIS (see chapter 6 of the 2018 RIS):

- Ongoing review
- Mid-term review.

Ongoing review
As part of the broader SafeScript evaluation strategy outlined in the 2018 RIS, DH is conducting ongoing monitoring of the effectiveness of SafeScript via the collection and analysis of a range of data on a frequent basis. The new medicines included in SafeScript will be included in this ongoing monitoring. This includes reviewing externally collected data and evidence including the Australian Commission on Safety and Quality of Health Care's report *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21*[13] and evidence and recommendations provided in reports of the Coroners Court of Victoria.

[13] Australian Commission on Safety and Quality of Health Care, *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21*, available at https://www.safetyandquality.gov.au/our-work/healthcare-variation/opioid-medicines-dispensing-all-ages-2016-17-2020-21.

Data from SafeScript will be used to support ongoing monitoring and review. A key step for DH is to review the requirements and processes for collecting this data. This task has been delayed following the introduction of SafeScript in 2019 due to urgent reprioritisation of DH resourcing as a result of the COVID-19 pandemic.

Mid-term review

The new medicines included in SafeScript will be part of the mid-term review of SafeScript as described in section 6.6 of the 2018 RIS. This review will occur once sufficient data to assess the operation of SafeScript is available. It is noted that the review of SafeScript has been delayed due to the impact of the COVID-19 pandemic (including impacts on DH resourcing and priorities and impacts of the pandemic on drug-related harms).

The review will include assessment of whether:

- Inclusion of the medicines in SafeScript has achieved the intended objectives and benefits
- The costs and/or burdens placed on health professionals are higher or lower than anticipated
- There are any unintended costs, issues or other consequences that need to be addressed or managed.

1. Background

This section outlines the purpose of this RIS and provides background to the RTPM system SafeScript in Victoria.

1.1 Purpose of the RIS

The purpose of this RIS is to evaluate options for the inclusion of the medicines pregabalin, gabapentin and tramadol in the medicines monitored by Victoria's RTPM system, SafeScript.

Pregabalin and gabapentin are classed as gabapentinoids and used in the treatment of neuropathic pain (pain caused by an abnormality of, or damage to, the nerves) and epilepsy.[14] Tramadol is an opioid-like analgesic used for short-term relief of moderate to severe pain. The three medicines are listed on the PBS so can be dispensed to patients at a Government-subsidised price or can be obtained privately at full price.

The three medicines are included in Schedule 4 (Prescription Only Medicine) of the national Poisons Standard. The Poisons Standard is a legislative instrument prepared under the *Therapeutic Goods Act 1989 (Cwlth)*. Schedule 4 poisons can only be obtained from a registered health practitioner who is authorised to sell or supply, including to issue a prescription for, a Schedule 4 poison under the Act.

Pregabalin, gabapentin and tramadol have contributed to overdose deaths in Victoria, particularly pregabalin in the last five years, but none is monitored in SafeScript. Table 5 shows annual frequency of overdose deaths by contributing drug type plus alcohol and illegal drugs.[15] [16] The risk of harm from the three medicines is considered further in Chapter 2.[17]

[14] Australian Government Therapeutic Goods Administration, https://www.tga.gov.au/news/safety-alerts/pregabalin-and-gabapentin.

[15] Gabapentin is not included in the Coroners Court data set. Pregabalin and gabapentin are discussed together because they are in the same class, have same or similar risk profile, and would be substituted for each other in prescribing practices.

[16] Gabapentin is not included in the Coroners Court data set. Pregabalin and gabapentin are discussed together because they are in the same class, have same or similar risk profile, and would be substituted for each other in prescribing practices.

[17] In this RIS, pregabalin, gabapentin and tramadol are referred to as "medicines". The term "medicines" is also generally used when talking about drugs or poisons (which are terms used in the Act and *Therapeutic Goods Act 1989 (Cwlth)*). The terms "drugs" and "poisons" are used in some places in the RIS when referring to information or evidence from a source document (to be consistent with the source) or when a particular meaning is required that is not covered by "medicines".

Table 5 Annual frequency of overdose deaths where pregabalin and tramadol contributed plus major contributing pharmaceutical drug groups plus alcohol and illegal drugs, Victoria 2017-2021.

	2017	2018	2019	2020	2021
Benzodiazepines	303	304	285	284	266
Illegal drugs	267	260	274	276	260
Pharmaceutical opioids					
Tramadol	*32*	*35*	*37*	*28*	*20*
Other pharmaceutical opioids	166	172	170	164	162
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Alcohol	151	161	145	155	147
Antipsychotics	136	109	103	113	99
Anticonvulsants					
Pregabalin	*52*	*69*	*66*	*69*	*65*
Other anticonvulsants	23	18	19	23	20
Non-benzo anxiolytics	56	47	54	51	46
Non-opioid analgesics	38	40	50	37	21
Total	**1,420**	**1,411**	**1,373**	**1,381**	**1,265**

Source: Coroners Court of Victoria, Table 8, Victorian overdose deaths, 2012-2021.[18]

Including new medicines in SafeScript will require an amendment to Schedule 5 – Monitored poisons and Schedule 6 – Monitored supply poisons of the Regulations. Schedule 5 enables the collection of the medicines into SafeScript whereas Schedule 6 mandates the medicines that prescribers and pharmacists need to check in SafeScript before supplying.

Under section 7 of the *Subordinate Legislation Act 1994*, a RIS is required to be prepared for proposed regulations[19]. The responsible Minister must ensure a RIS is prepared for public consultation.

DH has engaged Sapere Research Group to prepare this RIS in accordance with BRV's Victorian Guide to Regulation[20] and the *Subordinate Legislation Act 1994*.

The analysis in this RIS relates to the inclusion of additional medicines to be monitored in Victoria's RTPM system. It is noted that a RIS was produced in 2018 to assess options for establishing Victoria's new RTPM system, including the medicines to be monitored in the RTPM system (referred to in document as the 2018 RIS). The 2018 RIS is available on the BRV website.[21]

[18] Note the total calculated in this table is different to the total calculated in the source document.
[19] Unless there is an exemption under section 8 of the Subordinate Legislation Act.
[20] Office of the Commissioner for Better Regulation, 2016, Victorian Guide to Regulation: A handbook for policy makers in Victoria, Department of Treasury and Finance, Melbourne.
[21] Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018, available at https://www.vic.gov.au/regulatory-impact-statements-2018.

1.2 What is a RTPM system?

A RTPM system enables prescribing registered medical practitioners and nurse practitioners and dispensing pharmacists to access accurate and up-to-date information regarding a patient's medication history with respect to specific high-risk medicines in real time. A RTPM system enables patients' prescriptions and pharmacy dispensing records for certain high-risk medicines to be transmitted in real-time to a centralised database which can then be accessed by registered medical practitioners, nurse practitioners and pharmacists during a consultation.

This information helps clinicians make safer clinical decisions and reduces the incidence of harm, including death, from the use of pharmaceutical medicine. It is intended to reduce inappropriate multiple prescribing events (particularly by multiple providers), provide clinical alerts about opioid doses and prescribing of high-risk combination of medicines, and improve quality of care by facilitating a patient-centred approach in addressing prescription medication misuse.

1.3 Introduction of a RTPM system in Victoria

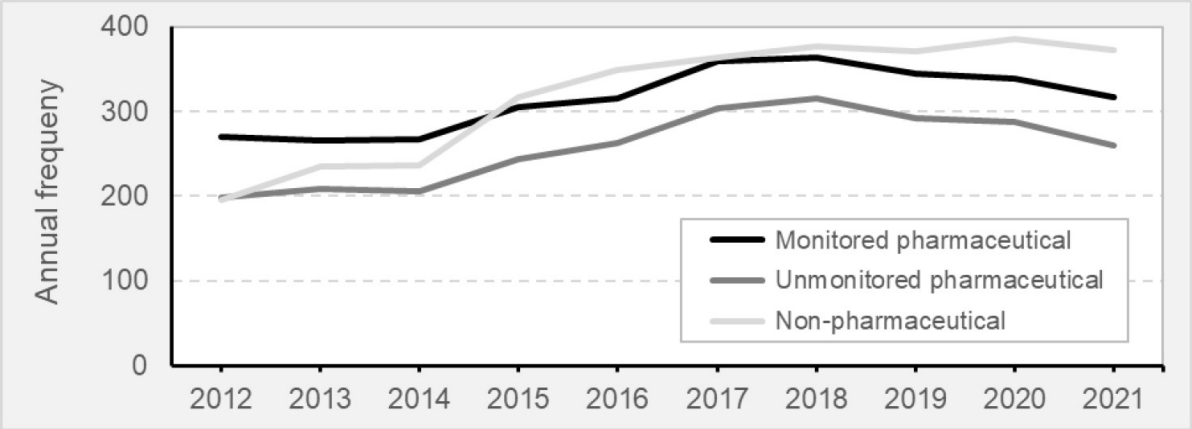
SafeScript is the Victorian Government's RTPM system and was introduced state-wide in April 2019 and became mandatory to use on 1 April 2020. SafeScript monitors prescription medicines identified as presenting the greatest risk of harm for the Victorian community.[22]

Data published by the Coroners Court of Victoria in its report *Victorian Overdose Deaths 2011-2021* shows a decline in the frequency of Victorian overdose deaths between 2018 and 2019 which it notes appears to be driven largely by a decline in the number of fatal overdoses involving pharmaceutical drugs monitored in SafeScript since it was introduced. Figure 1 shows a graph produced by the Coroners Court of Victoria showing the frequency of overdose deaths involving drugs monitored in SafeScript, pharmaceutical drugs not monitored in SafeScript, and non-pharmaceutical drugs from 2012 to 2021. The Coroners Court of Victoria notes:

> *'Specifically, there was a historical increasing trend over time between 2011 and 2018 in the annual frequency of Victorian overdose deaths involving pharmaceutical drugs tracked by SafeScript as well pharmaceutical drugs not tracked by SafeScript, but in 2019 and 2020 this trend was reversed. This reversal coincided with the 2018 SafeScript implementation…there may be many explanations for these findings, but the 2019 and 2020 interruption to the historical increasing trend in overdose deaths is a cautiously positive result…the decreasing trend has continued into 2021…'*[23]

[22] RPTM referred to as SafeScript from this section onwards in the RIS.
[23] Coroners Court of Victoria, *Victorian Overdose Deaths 2021-2021*, 22 August 2022, p.17.

Figure 1 Annual frequency of overdose deaths involving drugs monitored in SafeScript, pharmaceutical drugs not monitored in SafeScript, and non-pharmaceutical drugs, Victoria 2012-2021



1.3.1 SafeScript

SafeScript is a web-based centralised IT database that contains real-time prescribing and dispensing records of monitored medicines for patients in Victoria that can be accessed by prescribers and pharmacists during a consultation.

The data required for SafeScript is collected automatically from prescription exchange services that support the electronic transfer of prescription information from the medical practitioner or nurse practitioner to SafeScript from where it can be accessed by a pharmacist. When a prescription is supplied or dispensed, the prescription exchange services will send a record of the prescription or supply in real time to SafeScript.

It allows prescribing and dispensing records for the high-risk medicines included in Schedule 5 and Schedule 6 to be transmitted in real-time to a centralised database which can then be accessed by registered medical practitioners, nurse practitioners and pharmacists during a consultation.

SafeScript is quick and easy-to-use and is integrated with existing practitioner prescribing and dispensing software. SafeScript is designed to be integrated into clinical workflows.

Registered medical practitioners, nurse practitioners and pharmacists have access to SafeScript to view records of all high-risk medicines in Schedule 6 that have been prescribed or supplied to patients under their care.

1.4 The regulatory framework for SafeScript

1.4.1 Overview

The supply of medicines in Victoria is governed by the Act and the Regulations. Together, the Act and the Regulations limit the manufacture, distribution and use of drugs, poisons and controlled substances to those people who are properly trained and equipped. They also provide regulatory controls on the sale, supply, including prescribing of medicines to promote safe patient management.

DH is responsible for administering the Act and the Regulations in Victoria.

In 2017 the *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Act 2017* was introduced to amend the Act to provide for the establishment of SafeScript including:

(a) a database relating to the monitoring of the supply of certain poisons and controlled substances; and

(b) information to be included on the database; and

(c) access to the database.

The Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018 amended the Regulations to prescribe:

(a) entities required to provide information to the monitored poisons database; and

(b) poisons which are to be monitored on the monitored poisons database; and

(c) exceptions to the requirement to check the monitored poisons database.[24]

Under the Act and the Regulations, Prescription Exchange Services[25] [26] are required to provide information to SafeScript in accordance with the Regulations. Pharmacists, registered medical practitioners, nurse practitioners and authorised suppliers[27] must check SafeScript for the records or information in relation to a person before supplying the monitored medicine for that person.[28]

Registered medical practitioners, nurse practitioners and pharmacists need to register as a user with SafeScript before they are given access to SafeScript. The system checks that they have a current registration with the Australian Health Practitioner Regulation Agency each time they log in. There are currently more than 33,700 registered users of SafeScript.

[24] Amended by the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.

[25] Prescribed in Schedule 4 of the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018. A PES is defined in the Regulations as a system that provides for the electronic transfer of prescription information between a person who issues a prescription and a pharmacist.

[26] Electronic Transfer of Prescription involves the creation of an electronic message (alongside a legal paper prescription) which is transmitted to a Prescription Exchange Service. A pharmacy can then dispense the medications from the paper prescription, but supported by electronically retrieving the prescription details from the prescription exchange service to improve efficiency and reduce the opportunity for errors transcribing prescription information from paper.

[27] Authorised supplier prescribed under section 30C of the Act, for example authorised DH staff.

[28] That is, before writing or dispensing a prescription.

Access to SafeScript is available to all registered clinicians through a secure web portal at www.safescript.vic.gov.au. This portal can also be accessed by prescribers who hand write prescriptions or who practise in a hospital. The SafeScript portal is accessible via PC or via a tablet or mobile device.

Authorised DH staff can also access SafeScript as part of their regulatory role in ensuring the safe supply of medicines in the community.

1.4.2 What medicines are monitored in SafeScript?

Monitored poison[29] means a Schedule 8 substance and any medicines listed in Schedule 5 of the Regulations. Medicines prescribed in Schedule 5 are:

- all benzodiazepines that are Schedule 4 poisons under the national Poisons Standard
- codeine when it is a Schedule 4 poison
- quetiapine
- zolpidem
- zopiclone.

Schedule 5 enables the collection of the monitored medicines into SafeScript.

Monitored supply poisons are prescribed in Schedule 6 of the Regulations and are:

- all Schedule 8 poisons under the national Poisons Standard[30]
- all benzodiazepines that are Schedule 4 poisons under the national Poisons Standard
- codeine when it is a Schedule 4 poison
- quetiapine
- zolpidem
- zopiclone.

Schedule 6 mandates the medicines that prescribers and pharmacists need to check before supplying.

Table 6 categorises the medicines monitored in SafeScript according to type.

[29] The Act uses the term "poisons" to refer to medicines regulated under SafeScript but as noted this RIS generally uses the term "medicines". Poisons has been used here for consistency with the language used in the Act.

[30] All medicines registered for use in Australia must be approved by the TGA. The TGA also oversees the classification of medicines in Australia into one of several schedules, according to the level of regulatory control required to ensure public health and safety. Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. A valid prescription is required for both Schedule 4 - Prescription Only Medicines - and Schedule 8 (S8) - Controlled Drug Medicines - according to the TGA's Standard for the Uniform Scheduling of Medicines and Poisons.

Table 6 Medicines monitored in SafeScript[31]

Type of medicine	Medicine
Strong opioid painkillers	Buprenorphine, Codeine (including combination codeine medicines), Fentanyl, Hydromorphone, Methadone, Morphine, Oxycodone, Pethidine, Tapentadol.
Strong medicines for anxiety or sleeping tablets (benzodiazepines)	Alprazolam, Flunitrazepam, Bromazepam, Clobazam, Clonazepam, Diazepam, Lorazepam, Midazolam, Nitrazepam, Oxazepam, Temazepam.
Other strong sleeping tablets	Zolpidem, Zopiclone.
Stimulants for ADHD or narcolepsy	Dexamfetamine, Lisdexamfetamine, Methylphenidate.
Other high-risk medicines	Ketamine, Quetiapine.

The medicines included in Schedule 5 and Schedule 6 are monitored in SafeScript.

1.4.3 How were medicines initially selected for monitoring in SafeScript?

All Schedule 8 medicines have been included for monitoring, as they carry the highest level of risk and have additional controls on their supply.

To select the Schedule 4 medicines for monitoring, in 2017 DH commissioned Austin Health to develop an evidence base into which other medicines should be monitored in SafeScript based on their potential for harm. Austin Health's analysis and findings are presented in its report *Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system*[32] (Initial Report). As part of this, Austin Health conducted a literature review which included extensive quantitative and qualitative analysis including data from Ambulance Victoria, Victorian Coroners Prevention Unit, National Coronial Information System, Victorian Poisons Information Centre, and Victoria Police Forensic Services Department. The findings were considered by DH's

[31] This table shows the most commonly prescribed Schedule 8 medicines. There are some other Schedule 8 medicines but not all are registered in Australia.

[32] Department of Clinical Pharmacology and Therapeutics and Pharmacy Department Austin Health, Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system, March 2017.

SafeScript External Advisory Group[33] (which included key medical and pharmacy organisations) which made recommendations that were accepted by the Victorian Government.

In advance to SafeScript becoming mandatory in April 2020, DH commissioned Austin Health to undertake an update of the literature review in early 2019 to determine if there was any significant new evidence of harm associated with medicines not monitored in SafeScript. Austin Health's analysis and findings are presented in its report *Evidence to inform the inclusion of additional Schedule 4 prescription medications on the Victorian real-time prescription monitoring system: an updated report* (2019 Austin Health review).[34] These findings were then reviewed by the SafeScript External Advisory Group.

Austin Health examined local data for fourteen medicines in the 2019 Austin Health review including pregabalin, gabapentin and tramadol[35]. The three main factors that were used by Austin Health in selecting medications to be examined in local data regarding definite harm, in order of descending importance:

- Peer-reviewed literature: local and key international literature regarding definite harm
- Peer-reviewed literature: local and international literature regarding misuse, abuse and addiction, and other international literature regarding harm
- Precedent from other prescription drug monitoring programs.

Consideration was also given to evidence previously collected in the Initial Report.[36] In relation to pregabalin and gabapentin, Austin Health said:

> *'the case for pregabalin remains open to interpretation…the External Advisory Group at this time will have to make a decision to act or wait based on context and a nuanced interpretation of the data and its associated considerations. Should it remain unmonitored, then it should still remain of possible concern in the future and ongoing assessments should track the evolution of pregabalin-related harm… This report recommends that if pregabalin was to be monitored, gabapentin should be too.'*[37]

In relation to tramadol, Austin Health said:

> *'There are now a plethora of studies regarding tramadol-related misuse, abuse and addiction, although translation to tramadol-related death is less certain…Importantly, local data suggests low levels of tramadol-related harm at present…If these metrics are correct in estimating a low risk of definite harm from tramadol, then it may be desirable that tramadol remains not*

[33] The SafeScript External Advisory Group concluded its work and was dissolved following implementation of SafeScript in 2019. The Department's Expert Advisory Committee on potential misuse of drugs of dependence now provides clinical governance regarding SafeScript.

[34] Medicines Optimisation Service Austin Health (Pharmacy Department and the Department of Clinical Pharmacology and Therapeutics at Austin Health), *Evidence to inform the inclusion of additional Schedule 4 prescription medications on the Victorian real-time prescription monitoring system: an updated report*, May 2019. After this footnote this review is referenced in this RIS as "2019 Austin Health Review".

[35] The fourteen medicines were pregabalin, gabapentin, tramadol, olanzapine, risperidone, mirtazapine, amitriptyline, desvenlafaxine, duloxetine, baclofen, venlafaxine, bupropion, and quetiapine.

[36] 2019 Austin Health review, p.29.

[37] 2019 Austin Health review, p.108.

monitored, to accommodate the case that tramadol has other riskier opioid use substituted to it following state-wide mandatory implementation of the RTPM[38] [39]

The SafeScript External Advisory Group did not recommend any additional medicines be added to the list of those monitored at the time.

1.5 Updated review of the medicines pregabalin, gabapentin and tramadol

In 2021 DH commissioned an updated review of literature (2021 Austin Health review) in relation to pregabalin, gabapentin and tramadol in response to feedback from stakeholders and potentially new evidence of harm for these medicines.[40] [41] Since 2019, several other Australian states and territories decided to include these medicines as monitored medicines in their RTPM systems (see 1.7 1.4.3 for discussion of other jurisdictions).

The 2021 Austin Health review was designed to inform a decision as to whether pregabalin, gabapentin and tramadol should be included in SafeScript. The review found that while overall metrics of death are not remarkable and have not changed since the 2019 Austin Health review, the role of pregabalin and gabapentin as an indicator of high-risk opioid use, added to the spectrum of harms associated with it, provide a compelling rationale to prioritise inclusion of gabapentinoids on SafeScript.[42] The 2021 Austin Health review found that harms exist for tramadol but that the case for inclusion is less compelling than for pregabalin and gabapentin.[43] Chapter 2 (Problem analysis) outlines the evidence of the problem in further detail.

The 2021 Austin Health review noted that SafeScript had been well implemented and well accepted by practitioners before and after the most challenging of times for healthcare in Victoria during the COVID-19 pandemic and was universally seen as useful and necessary. It also noted that it was not surprising that other states had followed its lead.[44]

DH's Expert Advisory Committee on potential misuse of drugs of dependence, which took over the clinical governance from the SafeScript External Advisory Group, supports the inclusion of the three medicines into SafeScript.[45]

[38] Referring to introduction of the mandatory RTPM system in April 2020.
[39] 2019 Austin Health review, p.109.
[40] Medicines Optimisation Service Austin Health (Pharmacy Department and the Department of Clinical Pharmacology and Therapeutics at Austin Health), *Evidence informing the inclusion of gabapentinoids and tramadol on Victoria's SafeScript: a 2021 update*, December 2021. After this footnote this review is referenced in this RIS as "2021 Austin Health Review".
[41] Note that the 2021 was intended as complementary and as an update to the first two reports and should be read together.
[42] 2021 Austin Health review p.1.
[43] 2021 Austin Health review, p.1.
[44] 2021 Austin Health Review, p.91.
[45] DH established an Expert Advisory Committee on potential misuse of drugs of dependence in 2018 consisting of clinical and content experts from the alcohol and other drug sector. The purpose of this group is to provide advice on the safe and effective management of all drugs of dependence for the Victorian community.

This RIS is being undertaken to consider options and undertake cost-benefit analysis of the proposed inclusion of the three medicines.

1.6 Other jurisdictions

The Commonwealth, state and territory health authorities are working together to implement a national RTPM system known as the National Data Exchange (NDE), which is based on Victoria's SafeScript. Its key objective is to enable real-time data-sharing between jurisdictions. This would enable practitioners to access patient data in a consistent way across the same medicines from all states and territories and for Commonwealth and state and territory health authorities to monitor trends in usage.

All states and territories have formally agreed to participate in the NDE. Victoria joined the NDE in July 2020. However, each state and territory remains responsible for the management of its own RTPM system and the medicines monitored within its jurisdiction. The high-risk medicines currently being monitored in each jurisdiction are determined individually by each state and territory.

Table 7 sets out the medicines that are currently included in each state and territory RTPM system. The monitored medicines are generally consistent between the states and territories. In relation specifically to the three medicines considered in this RIS, the ACT, Queensland, South Australia, and Northern Territory all include tramadol, gabapentin and pregabalin. NSW includes tramadol and pregabalin, but not gabapentin. Tasmania includes tramadol but not pregabalin and gabapentin. Western Australia has a non-mandatory prescription monitoring program that only includes Schedule 8 poisons but has flagged a new system will be introduced in coming years.

Given the coverage of these medicines in other states and territories it is timely for Victoria to consider whether tramadol and the gabapentinoids should be monitored in Victoria, taking into account the currently available evidence and CBA as well as harmonisation for data-sharing.

Table 7 RTPM systems in other jurisdictions

State or territory	Overview	Included medicines	Comparison to Victoria
Australian Capital Territory	Canberra Script is the ACT's real time prescription monitoring system.[46] The relevant legislation is the *Medicines, Poisons and Therapeutic Goods Act 2008*. Currently monitored medicines, which include tramadol, gabapentin and pregabalin, were declared by the Minister for Health "due to evidence of harms including deaths	Monitored medicines are: • Opioids including codeine • tramadol • all benzodiazepines • quetiapine • zolpidem and zopiclone • gabapentin and pregabalin.	Includes gabapentin, pregabalin and tramadol which are not included in Victoria.

[46] ACT Health, https://www.health.act.gov.au/canberrascript.

State or territory	Overview	Included medicines	Comparison to Victoria
	associated with their abuse and misuse in the Australian community".		
New South Wales	SafeScript NSW is the RTPM system used and was made available to prescribers and pharmacists across NSW in May 2022. The Poisons and Therapeutic Goods Regulation 2008 establishes the RTPM system in NSW. The current list of monitored medicines includes tramadol and pregabalin, but not gabapentin. According to the NSW Department of Health website, NSW Health will monitor usage trends of medicines that were considered but ultimately not included in the monitored medicines list, and any emerging evidence may warrant reconsideration of their inclusion in the SafeScript NSW system[47].	Monitored medicines are: • opioids (including tramadol) • all benzodiazepines • zolpidem and zopiclone • dexamfetamine, lisdexamfetamine, methylphenidate • ketamine, pregabalin, quetiapine • all other Schedule 8 medicines not listed above.[48]	Includes pregabalin and tramadol which are not included in Victoria.
Queensland	QScript is Queensland's RTPM system. The relevant legislation is the *Medicines and Poisons Act 2019*, introduced in 2021. Pregabalin, gabapentin and tramadol are included in the monitored medicines. Queensland Health states that the list of monitored medicines has been determined based on local and international research and incorporates the recommendations of a multi-disciplinary working party. Numerous factors were	Monitored medicines are: • all Schedule 8 medicines • all benzodiazepines • all Schedule 4 medicines that contain codeine • gabapentin and pregabalin • quetiapine • tramadol • zolpidem and zopiclone.	Includes pregabalin, gabapentin and tramadol which are not included in Victoria.

[47] Safescript NSW, https://www.safescript.health.nsw.gov.au/health-practitioners/about-safescript-nsw/what-is-safescript-nsw
[48] A full list of monitored medicines is included in the NSW Poisons and Therapeutic Goods Regulation 2008 Appendix E.

State or territory	Overview	Included medicines	Comparison to Victoria
	considered when determining whether a medicine was suitable for inclusion in the list, including the evidence of harm (on its own or in combination with other substances) and trends in prescribing, misuse, and abuse.[49]		
South Australia	ScriptCheckSA is South Australia's RTPM system. The relevant legislation is the *Controlled Substances Act 1984*. SA Health states that prescription medicines that cause the greatest harm to the South Australian community are monitored by ScriptCheckSA.[50] The system became mandatory in 2022.	Monitored medicines are: • all Schedule 8 medicines • all benzodiazepines • all S4 medicines that contain codeine • gabapentin and pregabalin • quetiapine • tramadol • zolpidem and zopiclone.[51]	Includes pregabalin, gabapentin and tramadol which are not included in Victoria.
Tasmania	Tasmania current uses DAPIS Online Remote Access (DORA) as its RTPM. Tasmania was the first state to implement RTPM in 2009.[52] The relevant legislation is the *Poisons Act 1971*. Pregabalin and gabapentin are not currently monitored.	Monitored medicines are: • all Schedule 8 medicines • Schedule 4 Appendix D opioids[53] (codeine, tramadol, and dextropropoxyphene).	Includes tramadol which is not included in Victoria
Western Australia	Western Australia currently operates a comprehensive prescription monitoring program that has been in place for many years. This collects all dispensing data relating to Schedule 8 medicines from community	n/a	n/a

[49] Queensland Health, https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/real-time-reporting/about-qscript.
[50] SA Health, https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/medicines+and+drugs/drugs+of+dependence/ScriptCheckSA+real+time+prescription+monitoring+in+South+Australia.
[51] Under the Controlled Substances (Poisons) Regulations 2011.
[52] Tasmanian Department of Health, https://www.health.tas.gov.au/health-topics/medicines-and-poisons-regulation/medicines-and-poisons-regulation-information-health-professionals/real-time-prescription-monitoring.
[53] Included in 2018.

State or territory	Overview	Included medicines	Comparison to Victoria
	pharmacies. The data is made available to health practitioners via a telephone information service. However, the system is not mandatory for practitioners. The Government has flagged a new RTPM will be introduced in coming years however limited details are available.[54]		
Northern Territory	NTScript is RTPM system introduced in the Northern Territory under the *Medicines, Poisons and Therapeutic Goods Act 2012*. Medicines monitored under the Act includes all TGA Schedule 8 substances and any other Scheduled substance prescribed by regulation. Pregabalin, gabapentin and tramadol are included in the monitored medicines. NT Health states that monitored medicines in addition to Schedule 8 poisons have a recognised risk of overuse, overdose and death and as such have been recommended by experts to be included in RTPM systems.[55]	Monitored medicines are: • Schedule 8 medicines • all benzodiazepines • codeine • gabapentin • pregabalin • quetiapine • tramadol.[56]	Includes pregabalin, gabapentin and tramadol which are not included in Victoria

1.7 RIS process

The key purpose of this RIS is to assess the impact of different options to address the risk of harm associated with pregabalin, gabapentin and tramadol. The rigorous assessment of regulatory proposals within a RIS ensures that regulation best serves the Victorian community. The general approach to the assessment was as follows:

[54] WA Department of Health, https://ww2.health.wa.gov.au/Articles/N_R/Prescription-monitoring-in-Western-Australia.
[55] NT Health, https://health.nt.gov.au/professionals/medicines-and-poisons-control2/ntscript-information-for-health-professionals.
[56] Section 81C of the Medicines, Poisons and Therapeutic Goods Regulations 2014 prescribes the Scheduled substances.

(1) Identification of the problem (chapter 2)

This involved consideration of the nature and extent of the problem that the proposed change to the Regulations aims to address, including the need for government intervention, the risks of non-intervention and the objectives of such intervention.

(2) Identification of options to achieve the objectives of the proposed change to the Regulations (chapter 3)

Two Options that could address the defined problems were identified. Options which were deemed less feasible or less relevant were identified but not pursued any further.

(3) Assessment of the costs and benefits, and identification of preferred option

Assessment of the costs and benefits under all options, relative to a Base Case of no regulations, was undertaken consistent with the requirements of BRV's Victorian Guide to Regulation.

Based on the analysis undertaken, a preferred option was identified.

(4) Assessment of other impacts

We have considered the likely small business and competition impacts of the preferred option.

(5) Implementation and evaluation

The arrangements for implementation and evaluation of the preferred option are described.

Findings from stakeholder consultation undertaken by DH to support consideration of options is outlined in Appendix A.

1.7.1 Public Comment

The proposed changes to the Regulations and this RIS will be released for public comment for a minimum of 28 days. The process for responding to the RIS is outlined in the Foreword to this report.

DH welcomes and will consider all submissions received during the period of public comment. DH will prepare a formal Response to Public Comment summarising the submissions received and its response. The formal Response to Public Comment document will be made available on the Medicines and Poisons Regulation website.

2. Problem analysis

This chapter describes the risks of misuse and harm from pregabalin, gabapentin and tramadol and the need for regulation of these medicines to manage the risks

The problem being addressed in this RIS is the residual risk of harms associated with pregabalin, gabapentin and tramadol, which are not currently monitored in SafeScript. Lack of monitoring of these medicines may contribute to their inappropriate prescribing and supply, resulting in risks of harm including overdose death.

We primarily utilise evidence from the Austin Health literature reviews and Victorian Coroners Reports. Additional primary research and review of specific reports and data sets from Australia and overseas is not undertaken because the Austin Health 2021 report provides a detailed review of the available primary evidence and places the evidence into appropriate context, particularly taking into account the varying clinical practices and regulatory frameworks in different jurisdictions. It is also noted that implementation of a RPTM system is in its early stages in other Australian jurisdictions.

2.1 Costs to society caused by misuse of high-risk prescription medicines

The impact of harms caused by high-risk prescription medicines range from poorer quality of life and absence from work, to in more extreme cases, criminal activity, hospitalisation and/or death. While there is limited or no research available on the social and economic costs to society of harms specifically in relation to the medicines pregabalin, gabapentin and tramadol, there is substantial literature and evidence available on the costs to society of high-risk prescription medicines more broadly. While the harms and costs differ across medicines, the broader evidence illustrates the types of costs and scale of costs associated with misuse of high-risk prescription drugs.

The National Drug Research Institute at Curtin University published a study in 2020, *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, which estimated the social and economic cost of extra-medical opioid use to Australia in 2015-16 was around $15.7 billion and that opioid use caused more than 2,200 deaths a year.[57] 'Extra-medical' opioid use was defined in the study includes the illegal use of heroin and the misuse of pharmaceutical opioids (use 'not as prescribed'). The cost included:

[57] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16,* Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University.

- $5.6 billion in direct tangible costs, including healthcare costs of $1.08 billion, costs of reduced productivity and worker absence of $$459 million, costs of drug-related crime of $936 million, and costs of road traffic accidents of $481 million.
- $10.1 billion in intangible costs, due to the premature death of 2,203 people and over 70,000 years of life lost. [58]

It is noted that given the Curtin University study includes the costs associated with a broader range of drugs including illicit drugs it is likely to represent higher costs than would be associated with misuse of pregabalin, gabapentin and tramadol, however it still represents a useful benchmark.

Similar research findings are made in overseas jurisdictions. A United States study, *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States*, found the total economic burden is estimated to be $78.5 billion for 2013. Over one third of this amount is due to increased health care and substance abuse treatment costs ($28.9 billion). Approximately one quarter of the cost is borne by the public sector in health care, substance abuse treatment, and criminal justice costs.[59]

2.2 Pregabalin and gabapentin

Pregabalin and gabapentin are classed as gabapentinoids and used in the treatment of neuropathic pain (pain caused by an abnormality of, or damage to, the nerves) and epilepsy.[60] They are discussed together because they are in the same class, have the same or similar risk profile, and would be substituted for each other in prescribing practices. Only including pregabalin in SafeScript could lead to substitution towards gabapentin, as discussed in the 2021 Austin Health review[61]. The evidence of the problem focuses on pregabalin as pregabalin usage comprises most of the gabapentinoid usage in Australia and there is more Australian evidence to support harms of pregabalin use than gabapentin (see prescribing data in section 2.1.2).

Pregabalin and gabapentin are Schedule 4 medicines and can only be obtained with a prescription from a registered medical practitioner or a registered nurse practitioner.

[58] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16,* Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University.

[59] *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States*, 2013
Curtis Florence, PhD, Feijun Luo, PhD, Likang Xu, MD, and Chao Zhou, PhD (National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Atlanta, Georgia, USA). Published in final edited form as: Med Care. 2016 October ; 54(10): 901–906. doi:10.1097/MLR.0000000000000625.

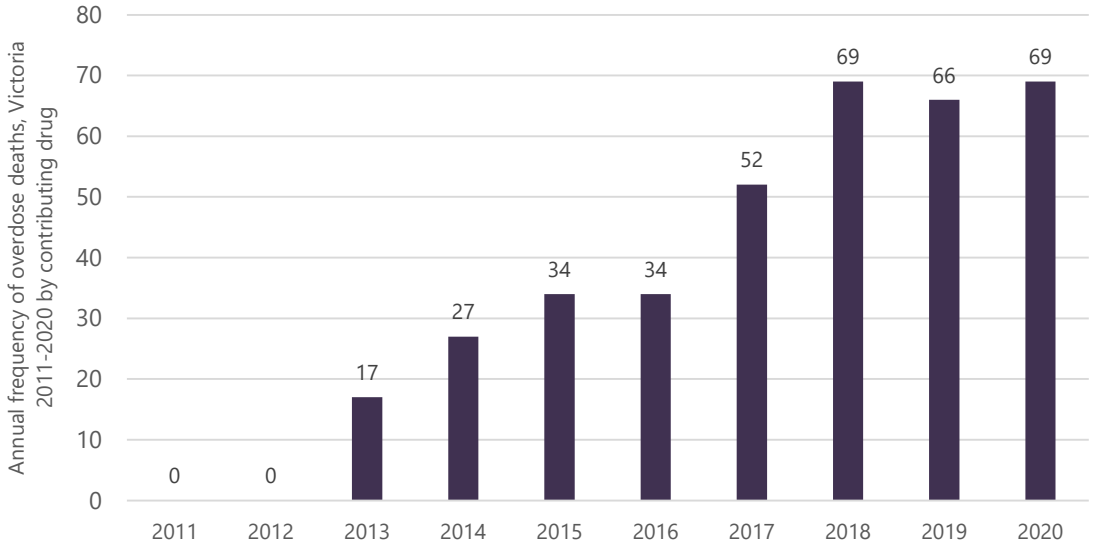
[60] Australian Government Therapeutic Goods Administration, https://www.tga.gov.au/news/safety-alerts/pregabalin-and-gabapentin.

[61] 2021 Austin Health review (p. 1) noted 'It is worth reiterating that including one gabapentinoid but not another would be merely to invite the substitution effect. This has been seen elsewhere and is likely to hold in Victoria.'

2.2.1 Harms caused by pregabalin and gabapentin

Figure 2 shows overdose deaths for pregabalin from 2011 to 2020. The number of overdose deaths caused by pregabalin increased from 15 in 2011 to 69 in 2020.

Figure 2 Victorian overdose deaths where pregabalin contributed, 2011 to 2020



Source: Coroners Court of Victoria. (2021)

The 2021 Austin Health review summarises Australian evidence in regard to the relationship between the use of pregabalin and opioid related deaths:

> ''*in Victorian data regarding overdose deaths, metrics for pregabalin have not followed an increasing trend from 2018 but have in fact remained stable, both in absolute and normalised terms. This may well correspond with maturity of overall use of pregabalin following the dramatic rise in its utilisation following PBS Streamline listing…, and simultaneous clinical interest in its use.*'
>
> *'Opioids have been particularly present in pregabalin-attributable deaths. Pregabalin flags non-prescribed pharmaceutical opioid use in people who inject drugs. Most damningly, in well-executed Australian pharmaco-epidemiological data, the initiation of persistently high pregabalin use appears to be associated with often substantial increases in prescription opioid use. In local data we see the increasing presence of pregabalin in opioid-related deaths in a way which does not occur in a comparator. In fact, it seems to be the highest risk opioid-related harm that pregabalin finds itself present at, in a way not seen with less impactful harm or in utilisation.''*[62]

[62] 2021 Austin Health review, p.92.

The 2021 Austin Health review outlines significant international literature regarding the extent of misuse of gabapentinoids and potential links with death (irrespective of whether causality can be demonstrated), and other harms.[63]

The 2021 Austin Health review's summary and recommendation for pregabalin and gabapentin is:

> *'Gabapentinoids[64] presence is disproportionately represented in the most serious opioid-related harm compared to less serious harm and in prescription opioid utilisation; causality may be hard to determine, but presence is far clearer. The role of gabapentinoids as a surrogate to flag high-risk opioid use, added to the spectrum of harms associated with it, provide a compelling rationale to prioritise inclusion of gabapentinoids on SafeScript.'*[65]

Several Victorian coronial reports have provided evidence about prescription medication abuse in relation to pregabalin. Coronial reports into deaths associated with prescription medication abuse of pregabalin state that pregabalin and gabapentin could become addictive in patients with prior substance use disorder, particularly opioid-dependent patients (*Finding into death without inquest*, court reference *COR 2019 7144, Finding into death without inquest, court reference*, COR 2019). People who are drug dependent administer pregabalin and gabapentin to potentiate[66] experienced euphoria and reduce withdrawal symptoms. Pregabalin has a higher addiction risk compared to gabapentin due to its faster onset of action.[67]

The Victorian Coroners have in recent years repeatedly recommended the inclusion of pregabalin in the scope of drugs monitored in SafeScript to reduce the risk of harm associated with pregabalin.[68]

The Coroners Court of Victoria noted in a summary of overdose deaths from 2010-2019 that in deaths investigated by Victorian coroners, doctors have been found to prescribe pregabalin widely without regard to its risk of misuse and abuse.[69] This issue is not unique to Australia with research indicating use and misuse of pregabalin rising in other jurisdictions:

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[63] 2021 Austin Health review, p.21. Review references include: Evoy KE, Covvey JR, Peckham AM, Ochs L, Hultgren KE. *Reports of gabapentin and pregabalin abuse, misuse, dependence, or overdose: An analysis of the Food And Drug Administration Adverse Events Reporting System (FAERS)*. Res Social Adm Pharm. 2019;15(8):953-8; Rahman A, Kane J, Montastruc F, Renoux C. *Trends in new prescription of gabapentinoids and of coprescription with opioids in the 4 nations of the UK*, 1993-2017. Br J Clin Pharmacol. 2021;87(8):3349-53; Chen TC, Knaggs RD, Chen LC. *Association between opioid-related deaths and persistent opioid prescribing in primary care in England: A nested case-control study*. Br J Clin Pharmacol. 2021; Minhaj FS, Rappaport SH, Foster J, Gashlin LZ. *Predictors of Serious Opioid-Related Adverse Drug Events in Hospitalized Patients*. J Patient Saf. 2021;17(8):e1585-e8; Torrance N, Veluchamy A, Zhou Y, Fletcher EH, Moir E, Hebert HL, et al. *Trends in gabapentinoid prescribing, co-prescribing of opioids and benzodiazepines, and associated deaths in Scotland*. Br J Anaesth. 2020;125(2):159-67; Macleod J, Steer C, Tilling K, Cornish R, Marsden J, Millar T, et al. *Prescription of benzodiazepines, z-drugs, and gabapentinoids and mortality risk in people receiving opioid agonist treatment: Observational study based on the UK Clinical Practice Research Datalink and Office for National Statistics death records*. PLoS Med. 2019;16(11):e1002965; Kriikku P, Ojanperä I. *Pregabalin and gabapentin in non-opioid poisoning deaths*. Forensic Sci Int. 2021;324:110830. Mariottini C, Kriikku.

[64] Pregabalin and gabapentin are types of gabapentinoids. Pregabalin and gabapentin are the gabapentinoid medications primarily utilised in Australia.

[65] 2021 Austin Health review, p.1.

[66] Potentiate means increase the power, effect, or likelihood of something, especially a drug or physiological reaction.

[67] Coroners Court of Victoria, *Finding into death without inquest*, court reference *COR 2019 7144*, p.10, and Coroners Court of Victoria, *Finding into death without inquest, court reference*, COR 2019, p.11.

[68] Coroners Court of Victoria, *Coroners Court of Victoria, Victorian overdose deaths*, 2011-2020, 29 July 2021, p.21.

[69] *Coroners Prevention Unit Data Summary* Overdose deaths, Victoria 2010-2019

Pregabalin was ranked sixth in the top subsidised drugs in Australia in 2016-2017 [6]. Globally, Lyrica® (Pregabalin) was ranked 11th in the top pharmaceuticals by sales in 2015. With this increasing use comes concerns about potential for off-label use, high-risk use, and misuse. Indeed, extensive off-label use has been reported, as has supra-therapeutic prescribing. A Swedish study revealed that 8.5% of patients receiving pregabalin were dispensed more than the maximum dose (600mg/day). Similarly, in Denmark, 9.6% of pregabalin users received >600mg/day [4], while a UK study reported only 1% receiving >600mg/day.[70]

The Coroners Court of Victoria's *Victorian overdose deaths, 2011-2020* stated that pregabalin misuse and acute toxic effects feature in a substantial number of deaths investigated by Victorian coroners each year. The 69 deaths in 2020 was the equal highest annual frequency in the past decade. Pregabalin was the fifth most frequent contributing drug to Victorian deaths in 2020 after diazepam, heroin, alcohol and methamphetamine, just narrowly in front of methadone which contributed to 65 deaths.[71] In 2021 methadone was the fifth highest contributing drug to Victorian deaths with 67 deaths, while pregabalin contributed to 65 deaths and was 6th on the list.[72]

Separate Coroners Court of Victoria inquests reported growing concerns about increased prescribing and abuse of pregabalin and its contribution to overdose deaths in Victoria. The coronial findings reported that pregabalin was the sixth highest contributing drug in overdose deaths in 2019 behind diazepam, heroin, methamphetamine, methadone and alcohol.[73]

The TGA investigated continuing reports of misuse associated with pregabalin, and abuse and dependence associated with both pregabalin and gabapentin in Australia. The TGA noted that:

- The National Coronial Information System shows that deaths related to pregabalin rose from 16 in 2013 to 121 in 2016; the majority of which were unintentional.
- A Medical Journal of Australia study of ambulance data in 2018 found a tenfold increase in the rate of pregabalin-related ambulance attendances since 2012, with patients frequently misusing pregabalin with other sedating medicines.
- On 19 January 2021, the TGA's Database of Adverse Event Notifications included 184 and 18 reports of suspected abuse, misuse or dependence with pregabalin and gabapentin products respectively. There were 111 fatal cases and 110 of these identified pregabalin as a suspected medicine.[74]

[70] Cairns, R., Schaffer, A.L., Ryan, N., Pearson, S., & Buckley, N.A. (2018). Rising pregabalin use and misuse in Australia: trends in utilisation and intentional poisonings. Doi: 10.1111/add.14412

[71] Coroners Court of Victoria, *Victorian overdose deaths, 2011-2020*, 29 July 2021, p.21. See also Table 8 of this Coroners Court report.

[72] Ibid, Table 8.

[73] Coroners Court of Victoria, *Finding into death without inquest*, court reference *COR 2019 7144*, p.10, and Coroners Court of Victoria, *Finding into death without inquest, court reference*, COR 2019, p.11.

[74] TGA, *Pregabalin and gabapentin Safety advisory - enhanced warnings relating to abuse and dependence*, 1 February 2021, available at https://www.tga.gov.au/news/safety-alerts/pregabalin-and-gabapentin.

2.2.2 Trends in prescribing pregabalin and gabapentin

It is important to understand metrics of harm in terms of number of prescriptions supplied for the medicines being considered so that they can be compared across other medicines currently monitored or not monitored under SafeScript. This section therefore considers trends in prescribing of pregabalin and gabapentin.

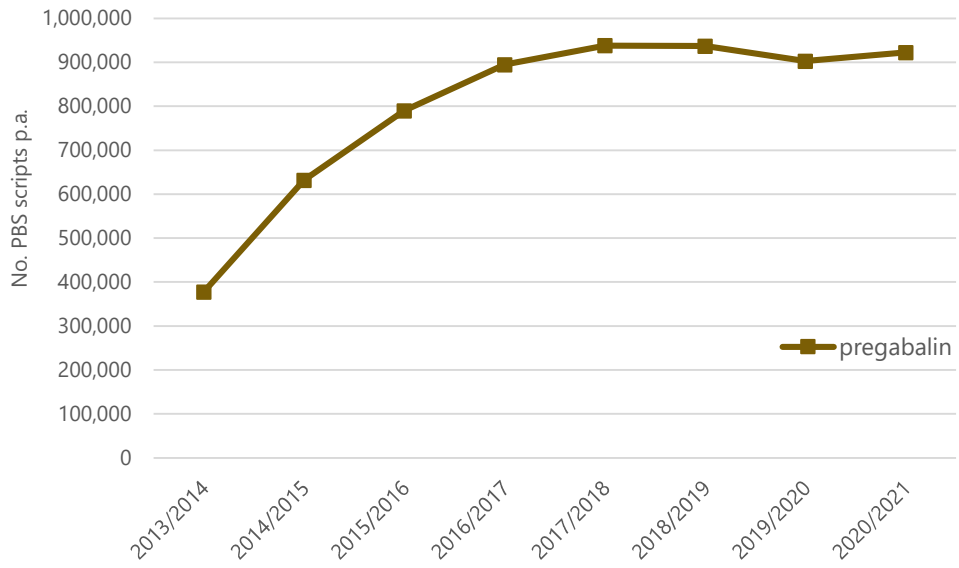
Figure 3 and Figure 4 show the number of PBS (subsidised) prescriptions supplied per year for pregabalin and gabapentin.

PBS prescriptions supplied for pregabalin more than doubled between 2013-14 and 2017-18, from just under 400,000 to just under 1 million, before stabilising through to 2020-21.

PBS prescriptions supplied for gabapentin increased by 50 per cent from about 30,000 in 2013-14 to about 45,000 in 2020-21.

The 2021 Austin Health review reported that pregabalin utilisation has plateaued in keeping with maturity of use given current regulatory restrictions. [75]

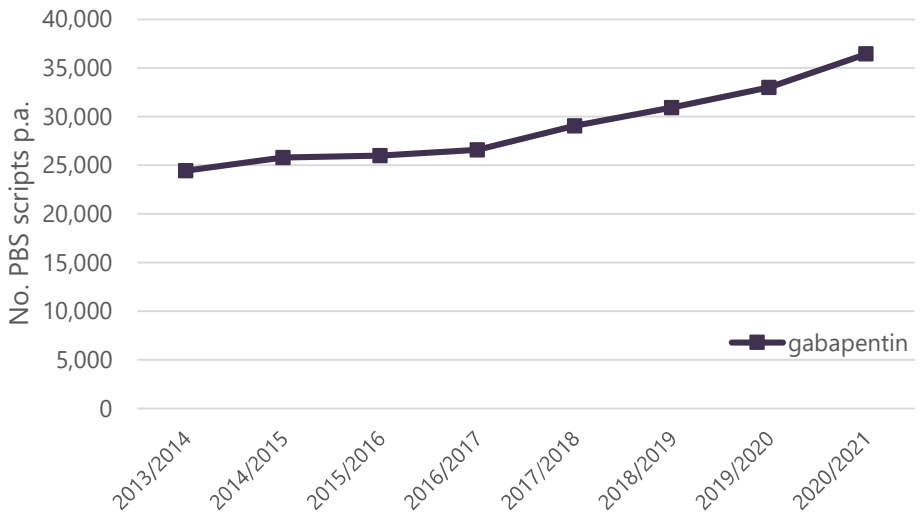
Figure 3 Number of prescriptions for pregabalin supplied per annum in Australia 2013-14 to 2020-21



Source: Data in Austin Health review. (2021).

[75] 2021 Austin Health review, p.31.

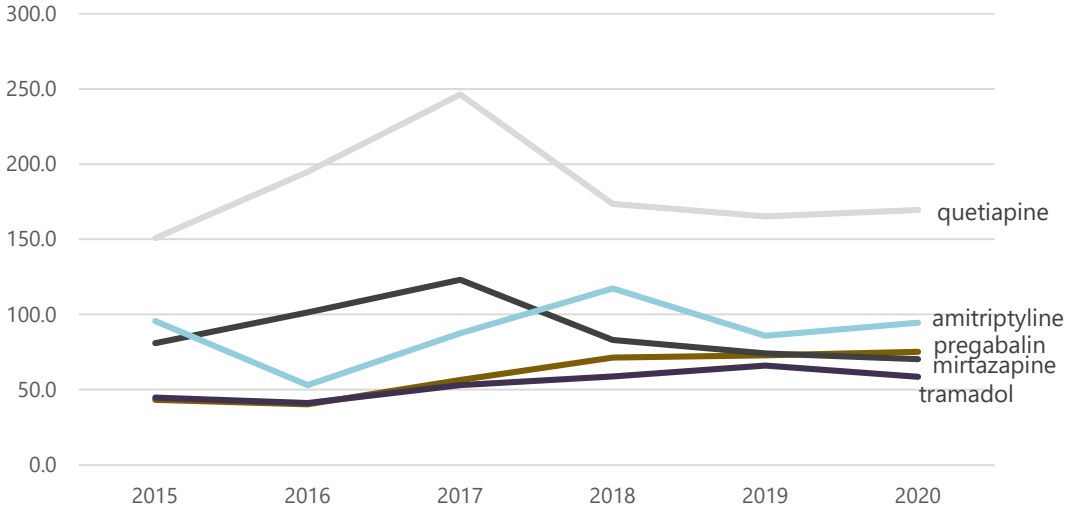
Figure 4 Number of prescriptions of gabapentin supplied per annum in Australia 2013-14 to 2020-21



Source: Data in Austin Health review. (2021).

As set out in the 2021 Austin Health review[76], Figure 5 shows the normalised index of harm (fatal toxicity index: deaths per million prescriptions) for pregabalin, tramadol and three other medicines (quetiapine, mirtazapine, and amitriptyline) during the period 2015 to 2020 in Victoria. These three medicines are Schedule 4 medicines and are used as comparators to contextualise indices of harm because they are medications which are often used in the same context, either in therapeutic use or in misuse, abuse, or misadventure. Gabapentin is not listed as it has low absolute numbers of death which can dramatically influence normalised indices.[77]

Figure 5 Normalised indices: deaths attributable to individual medications in Victoria

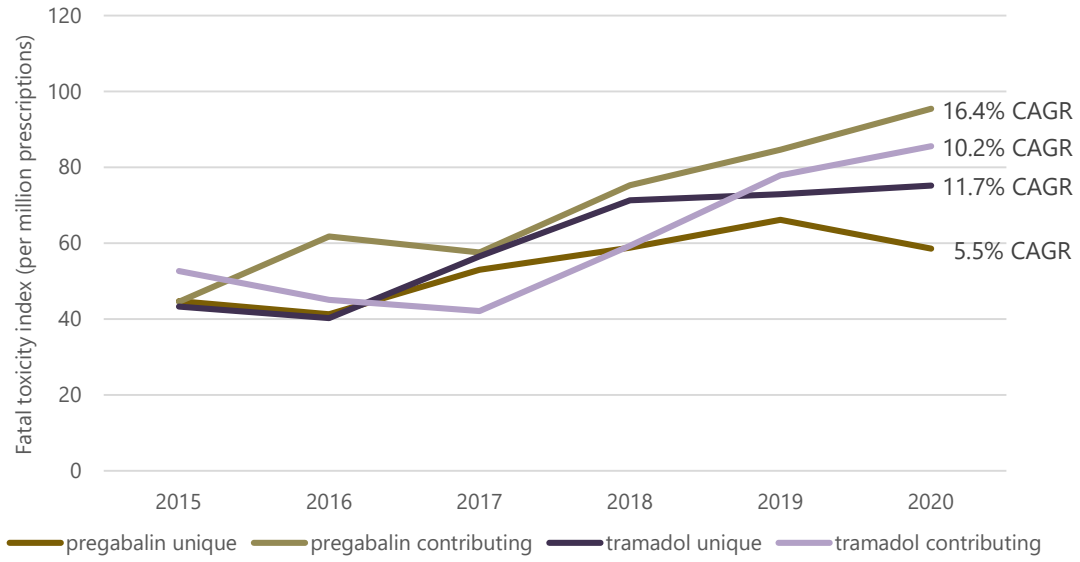


Source: Data sourced from table 5.2.1 of 2021 Austin Health review, which referenced the Coroners Court of Victoria Victorian Overdose Deaths Registry.

[76] 2021 Austin Health Review, pp35-36.
[77] 2021 Austin Health Review, pp35-36.

Figure 6 shows annual growth rates of fatal toxicity index for pregabalin and tramadol (unique overdose deaths and contributing as part of a combination of drugs).

Figure 6 Annual growth rate of fatal toxicity index for pregabalin and tramadol (also showing CAGR, see note below)



Note: Constant annual growth rate (CAGR) is the average rate of change over five years. For example: the figure suggests the fatal toxicity index for pregabalin contributing has risen on average by 16.4% p.a. between 2015 and 2020.
Source: Calculated by Sapere using data from table 5.2.1 of 2021 Austin Health review.

Quetiapine, currently monitored in SafeScript, has a significantly higher toxicity index than the four other medicines. The toxicity index for both pregabalin and tramadol increased slightly from 2015 to 2020. The 2021 Austin Health review noted the following trends:

- stabilised normalised indices of harm associated with pregabalin at a low-moderate level, substantially less than that for the SafeScript-included quetiapine and similar to that of mirtazapine and amitriptyline
- low normalised indices of harm associated with tramadol overall, which remain stable over the study period, demonstrating that no net effect was seen in terms of a substitution effect of use of high-risk opioid use flowing from monitored medicines to tramadol and leading to increased mortality associated with tramadol.[78]

Austin Health noted that while on overall normalised death rates alone, pregabalin and tramadol do not distinguish themselves from mirtazapine and amitriptyline and sit substantially below quetiapine, it is plausible that there are specific use cases where monitoring of pregabalin can provide important information to prescribers and dispensing pharmacists – particularly with combination toxicity with prescription opioids, and as a surrogate measure to flag high-risk opioid use.

[78] 2021 Austin Health Review, p.34.

2.2.3 Obtaining supplies of pregabalin beyond therapeutic need

As discussed in the 2018 RIS, problems with use of high-risk prescription medicines range from inadvertent harm associated with inappropriate prescribing practices through to deliberate misuse with the aim of experiencing nontherapeutic effects and/or on-selling the medicines. As such, there are many circumstances which can lead to prescription medicines ultimately causing harm to those that take them, including where patients obtain more medicines than are medically needed by attending multiple doctors and/or multiple pharmacies to obtain medications. This has been a contributing factor in recent overdose deaths in Victoria and has caused Victorian Coroners to recommend the inclusion of pregabalin in the list of medicines monitored in SafeScript in five different Coroners inquests from 2019 to 2021 (see examples in Text Box 1).[79]

Text box 1 Case studies – evidence from 2021 Coronial Inquests

Case study 1[80]

The medical cause of the person's death was combined drug toxicity involving pregabalin, dihydrocodeine, tramadol, temazepam, and lorazepam or (sic). The weight of available evidence supports a finding that the person was abusing a number of prescription medications for at least the last twelve months of his life and that he died from in the circumstances of an accidental or inadvertent overdose in combination with natural disease in the form of World Health Organisation class III obesity. The PBS patient summary for the person shows that in the last twelve months of life, that is between 14 May 2018 and 14 May 2019, he saw about 60 general practitioners, obtained prescriptions at about 38 consultations occasions and, on multiple occasions, attended two clinics on the same day.

Coronial recommendation: That DH review the circumstances of the person's death, and particularly the apparent ease with which he presented to multiple clinics, registered as a patient under false names and was prescribed significant quantities of drugs implicated in his death – pregabalin, tramadol, temazepam and lorazepam. Such review should include a re-consideration of the case for adding pregabalin to the list of medicines monitored through the SafeScript system and any other measures that could enhance patient safety in this regard.

Case study 2[81]

The person had a history of schizophrenia, post-traumatic stress disorder, bipolar disorder, asthma and Bart Pumphrey syndrome. Her hearing was impaired and during her lifetime, she had undergone cochlear implant surgery. The person had a long history of frequently visiting multiple general practitioners in quick succession citing neuralgic or neuropathic pain, amongst others, as her reason. The person was identified by Medicare under the Prescription Shopping Programme. Various medical practitioners were alerted to her propensity to visit numerous medical practitioners to request

[79] It is noted that the Coroner's inquest reports note a range of findings, some of which are not addressed by the proposed inclusion of the three medicines into SafeScript. For example, case study 1 is included to demonstrate the potential harms from misuse of pregabalin and risks of prescribing the medicine beyond therapeutic need, but the inclusion of pregabalin on SafeScript would not be able to prevent people obtaining pregabalin using false identities, which occurred in this case.

[80] Coroners Court of Victoria, *Finding into death without inquest,* court reference, COR 2019 2434.

[81] Coroners Court of Victoria, *Finding into death without inquest*, court reference COR 2019 7144.

analgesic medication. However, some medical practitioners discounted the alert because of the discrepancy in her date of birth or surname. Others, on the other hand, found her requests plausible due to the reasons cited for her request(s). The cause of death was reported as complications of a seizure in the setting of prescription medication abuse (pregabalin) The coronial report states that there is evidence indicating that:

- The person was successful in obtaining approximately 4,000 pregabalin tablets with relative ease in the three months immediately prior to her death
- Pregabalin was not a target drug monitored in SafeScript at the time when the person was able to obtain the tablets
- Medical practitioners who prescribed pregabalin did so without due regard to any risks associated with its misuse or abuse
- At the time of the person's death the Victorian Department of Health and Human Services (as the DH was then known) failed to cause pregabalin to be added to the list of drugs monitored by SafeScript, despite numerous opportunities to do so
- The ease with which pregabalin was available to the person and the timing of Medicare's Prescription Shopping Programme warning to alert the prescribers that she was prescription shopping correlates to the failure to monitor the drug on SafeScript.

Coronial recommendation:

- That DH review the circumstances of the person's death including but not necessarily limited to the apparent ease with which she presented to multiple clinics, registered as a patient under her maiden surname and altered date of birth and was prescribed significant quantities of pregabalin, implicated in her death.
- That DH's review should be expedited and aimed at including pregabalin to the list of medicines monitored through the SafeScript system and any other measures that could enhance patient safety in this regard.

2.3 Tramadol

Tramadol is a synthetic opioid, part of the "new generation" of opioids made from a chemical reaction rather than obtained from the opium poppy *(Papaver somniferum)* (such as morphine). Opioids are commonly used for the treatment of pain.

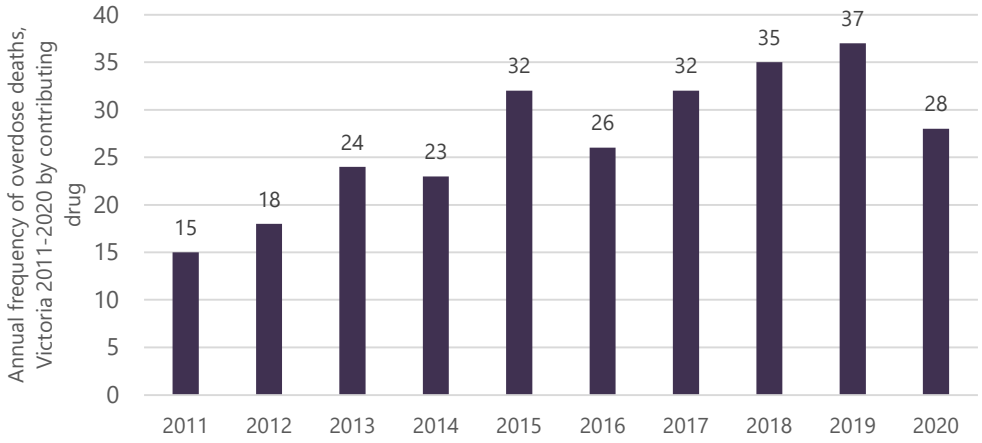
Tramadol is a Schedule 4 medicine and can only be obtained with a prescription from a registered medical practitioner or registered nurse practitioner. The 2021 Austin Health review noted that its use escalated rapidly globally in the early 2010s.[82] It remains one of the few commonly used opioids in Australia that is included in Schedule 4 rather than Schedule 8 (Controlled Drug) (combination codeine medicines being the other), and therefore not automatically monitored in SafeScript. Opioids included in Schedule 8 include buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone, tapentadol and pethidine.[83]

[82] 2021 Austin Health review, p.23.
[83] See national Poisons Standard for full list.

2.3.1 Harms caused by tramadol

This section looks at evidence of deaths due to overdose of tramadol. Figure 7 shows overdose deaths in Victoria for tramadol from 2011 to 2020. The number of overdose deaths from tramadol more than doubled from 15 in 2011 to 37 in 2019 before declining to 28 in 2020. It is noted that tramadol use declined in recent years, which possibly contributes to the decline in overdose deaths in 2020 – trends in usage are discussed further in section 2.2.2.

Figure 7 Victorian overdose deaths for tramadol, 2011 to 2020



Source: Coroners Court of Victoria. (2021)

In both the 2019 and 2021 Austin Health reviews, it was stated that there is now a plethora of studies regarding tramadol-related misuse, abuse and addiction, although translation to tramadol-related death is less certain.[84] The 2021 Austin Health review observes that what is clearer is that the non-death related harm associated with tramadol appears to be similar to that of other prescription opioids within the Australian context. In conclusion about the harms caused by tramadol, the 2021 Austin Health review states that:

> *'it is hard to make definitive conclusions about tramadol, but it would appear that the peer-reviewed literature finds it hard to distinguish tramadol from other prescription opioids. The review further notes that, given that context is critical, Australian data should be given greater weight, but these …fail to distinguish tramadol from other opioids at every step between ambulance attendances for extramedical use to hospital admission following opioid-related poisoning.'*[85]
>
> *'variations in context internationally limit their applicability. For example, while tramadol may have a case-fatality risk five times less than oxycodone or morphine in Ireland, such outcomes are an amalgam of pharmacological properties and clinical context, the latter of which varies between countries. Nevertheless, it should be noted that tramadol is frequently observed in*

[84] 2019 Austin Health review, p.108, and 2021 Austin Health review, p.93.
[85] 2021 Austin Health review, p.30.

intentional poisonings internationally, with all the caveats that varied regulation profiles might carry, and such poisoning reports have varying mortality associated with it. [86]

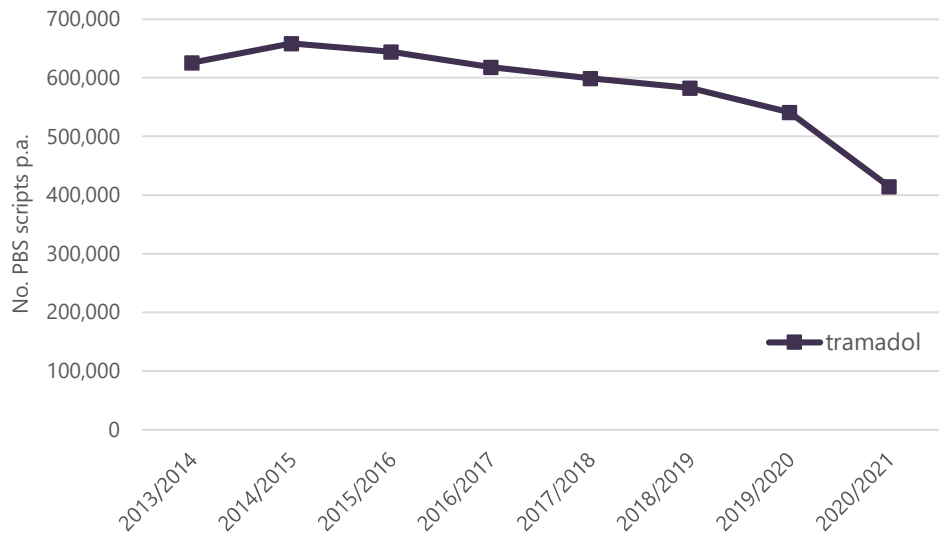
It is noted that there is less clarity in the research around the risks of tramadol than pregabalin and gabapentin. The TGA's Consultation Paper, *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response* examines the issues around prescription opioid use and misuse in Australia. It observes that following the rescheduling of codeine, the main Schedule 4 opioid used for analgesia in Australia is tramadol[87], and that while tramadol is one of the six opioids associated with accidental overdose fatalities in Australia, it is in Schedule 4 not Schedule 8. The TGA noted that the role of tramadol in therapy and the most appropriate indications may need to be clarified.[88]

2.3.2 Trends in prescribing tramadol

Figure 8 shows the number of PBS (subsidised) prescriptions supplied per year for tramadol.

The 2021 Austin Health review reported that tramadol use has declined in recent years, likely due to increased attention and regulatory changes to opioid prescribing.[89] [90]

Figure 8 Number of PBS prescriptions of tramadol supplied per annum in Australia 2013-14 to 2020-21



Source: Austin Health. (2021).

It is useful to put the use of tramadol into context compared to the use of other opioids in Australia. The TGA's consultation paper examining the issues around prescription opioid use and misuse in Australia noted:

[86] 2021 Austin Health review, p.30.
[87] (noting that neither dihydrocodeine nor dextropropoxyphene are commonly used in Australia).
[88] Therapeutic Goods Administration, *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response Consultation paper*, 2018, p.21.
[89] While not specifically outlined by Austin Health, regulatory changes include introduction of SafeScript.
[90] 2021 Austin Health review, p.31.

'In 2014, almost 3 million people in Australia were prescribed at least one opioid under the PBS or Repatriation PBS (RPBS). Since the end of 2009, there has been a general increase in prescriptions, from about 10 million annually to 14 million annually…Although codeine is the most widely prescribed opioid by number of prescriptions, in terms of Defined Daily Doses oxycodone is the most highly used opioid, followed by tramadol'. [91]

However, in more recent years there was a decline in opioids prescribed. The Australian Commission on Safety and Quality of Health Care's report *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21* describes that there was an 18% reduction in opioid medicines dispensing rates nationally between 2016–17 and 2020–21, reversing the trend for the period 2013–14 to 2016–17. The report states that the reduction in dispensing rates occurred despite all codeine-containing products becoming available on prescription only in February 2018 – a change that was expected to increase prescribing. The report observes that national and state initiatives, including regulatory changes to reduce the amount of opioid medicines supplied on each prescription, changes in clinical practice, prescription monitoring and medication stewardship programs, and educational programs highlighting new ways to manage pain, are likely to have contributed to the decrease in opioid medicines use.[92]

Figure 5 in section 2.2.2 shows the normalised index of harm (fatal toxicity index: deaths per million prescriptions) for pregabalin, tramadol and three comparator medicines (quetiapine, mirtazapine, and amitriptyline) during the period 2015 to 2020 in Victoria. It can be seen that tramadol had a significantly lower deaths per million prescriptions than quetiapine, and slightly lower than pregabalin, mirtazapine, and amitriptyline.

2.3.3 Obtaining supplies of medicines beyond therapeutic need

Compared to pregabalin and gabapentin we find that there is limited evidence about tramadol and whether it is being prescribed at a level beyond therapeutic need.

It was cited in a Victorian Coroner's inquest report, *Finding into death without inquest, court reference, COR 2019 2434*, as being one of the drugs present and causing combined drug toxicity causing death in a patient that had attended multiple practitioners and obtaining prescriptions on 38 occasions.[93]

After reviewing the 2021 Austin Health report, DH's Expert Advisory Committee's view was that tramadol should be included in SafeScript to help identify opioid dependence as it is often overprescribed in complex chronic pain and has strong addiction potential.

[91] Therapeutic Goods Administration, *Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response Consultation paper*, 2018, p.5.
[92] Australian Commission on Safety and Quality of Health Care, *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21*, available at https://www.safetyandquality.gov.au/our-work/healthcare-variation/opioid-medicines-dispensing-all-ages-2016-17-2020-21.
[93] Coroners Court of Victoria, *Finding into death without inquest, court reference, COR 2019 2434*.

2.4 Inconsistency with other states and territories

As discussed in section 1.6, the ACT, Queensland, South Australia, and Northern Territory all include tramadol, gabapentin and pregabalin. NSW includes tramadol and pregabalin, but not gabapentin. Tasmania includes tramadol but not pregabalin and gabapentin. Western Australia has a non-mandatory prescription monitoring program that only includes Schedule 8 poisons but has flagged a new system will be introduced in coming years. The states and territories are committed to development of a national RTPM system. Victoria stands out as the jurisdiction that does not monitor pregabalin, gabapentin or tramadol.

Lack of consistency in the medicines monitored under the respective state and territory RTPM systems, lessens the effectiveness of national data sharing across states and territories. It means practitioners are unable to access patient data in a consistent way across the same medicines from all States and Territories (when people may be prescription shopping across different jurisdictions). An important problem is for practitioners working in towns on the border of other states and territories where drug-seeking across the border needs be understood for a comprehensive assessment of the patient's record, or for patients newly arrived in the State from other jurisdictions or visiting other jurisdictions. It makes interpretation of national data more challenging and may lead to lack of clarity about risks of different medicines, for example understanding trends in usage and harms. It can also cause issues in relation to confusion for practitioners working across different jurisdictions, for example understanding what medicines need to be checked. Practitioners working across multiple jurisdictions need to learn and keep up to date with the different RTPM requirements in each state and territory. This is likely to impact a small number of general practitioners with only about 1 per cent of general practitioners moving between states and changing their principal place of practice each year[94] [95]

2.5 Objectives of the proposed Regulations

The main objective that DH aims to achieve through the legislation and the accompanying regulations, is a reduction in harm caused by pregabalin, gabapentin and tramadol. This outcome is expected to be achieved through a reduction in episodes of multiple prescribers and a reduction in the inappropriate supply of these medicines, increased visibility of what is being prescribed which leads to safer and more informed clinical decisions resulting in a reduction in deaths and injuries. Other objectives include:

- Increased benefits to medical practitioners due to reduced time required to treat patients as a result of having quick and ready access to information about prescribing and dispensing

[94] Soumya Mazumdar, *Ian McRae, Doctors on the move: National estimates of geographical mobility among general practitioners in Australia, 2015, available at* https://www.racgp.org.au/getattachment/cc47819b-53a9-4cf4-bfa1-76a5229591f8/Doctors-on-the-move-National-estimates-of-geog-2.aspx. Moving between states in this paper means changing principal place of residence.

[95] Although there are likely to be more practitioners working across jurisdictions than this number as some practitioners may practice across different states but not change their principal place of practice.

events of pregabalin, gabapentin and tramadol, thus supporting their decision about which medicines to prescribe.

- Increased consistency with RTPM systems in other states and territories, leading to benefits for medical practitioners working across jurisdictions or treating patients obtaining monitored medicines in multiple jurisdictions, and improved information to support understanding of the usage of the three medicines and associated harms.

3. Identify options

This chapter identifies the set of options considered for the proposed regulations and assesses the options.

As part of the RIS process, it is important to consider different options that could achieve the Victorian Government's objectives. The *Subordinate Legislation Act 1994*, the Subordinate Legislation Act Guidelines, and the Victorian Guide to Regulation recommend that this includes considering a range of approaches, including co-regulation and non-regulatory approaches, and those that reduce the burden imposed on business and/or the community.

Given the well-established regulatory framework for prescription medicines at both a Commonwealth and state and territory level, and Victoria's established RTPM system, SafeScript, the focus of this RIS is limited to considering pregabalin, gabapentin and tramadol for inclusion in SafeScript and does not consider options outside of this scope.

This RIS analyses three options:

- **Base Case**: no change to the medicines monitored in SafeScript
- **Option 1**: add pregabalin and gabapentin to the medicines monitored in SafeScript
- **Option 2**: add pregabalin, gabapentin and tramadol to the medicines monitored in SafeScript (Option 1 plus tramadol).

The impacts of Options 1 and 2 are assessed against the base case.

Addition of medicines to the list of medicines monitored in SafeScript requires amendments to Schedule 5 (monitored poisons) and Schedule 6 (monitored supply poisons) of the Regulations.

Pregabalin and gabapentin are grouped together in Option 1 because they are both in the gabapentinoid class of drugs which are prescribed to treat the same illnesses. It is not feasible to assess these medicines separately. The 2021 Austin Health observed:

> *"It is worth reiterating that including one gabapentinoid but not another would be merely to invite the substitution effect. This has been seen elsewhere and is likely to hold in Victoria."*[96]

Option 2 is included to explore the impact of adding tramadol to the monitored medicines in addition to pregabalin and gabapentin, reflecting that the use of tramadol and risks of harms is different to that of pregabalin and gabapentin.

The 2021 Austin Health review noted that alternative options to inclusion of medications as monitored supply poisons could include:

- inclusion only of higher dosage tablets for monitoring, with exemption for lower dosage tablets (e.g., for pregabalin 150mg and 300mg tablet prescriptions to be included, with exemption for pregabalin 25mg and 75mg tablet prescriptions, if it was shown that lower dosage tablets were less associated with high-risk use

[96] 2021 Austin Health review, p.1.

- the use of 'monitored poisons' (Schedule 5 of Regulations)[97] in addition to 'monitored supply poisons' (Schedule 6 of Regulations), to allow for monitoring of medications without mandatory checks[98]. This would have potential benefits for both prescribers of the medication, as well as prescribers of medications with potential combination toxicity (e.g., inclusion of pregabalin as a 'monitored poison' so that interested clinicians can determine whether patients are receiving pregabalin from other prescribers, but also so that prescribers of opioids to the same patient can determine that the patient has also been co-prescribed pregabalin with the potential for combination toxicity).

However, the review concluded that practically these alternatives are difficult to implement from an end user perspective and therefore could not be considered in lieu of blanket inclusion of a medication on SafeScript.

DH agrees with the conclusion of the 2021 Austin Health review and is not pursuing either of these options as feasible for the effective use of SafeScript. These options will not be explored in this RIS.

[97] Schedule 5 poisons are monitored while Schedule 6 poisons require mandatory checking.
[98] That is, some poisons might just be included in Schedule 5 for monitoring, and not in Schedule 6 for mandatory checks.

4. Options analysis

This chapter of the RIS analyses the options for changes to the Regulations to determine a preferred approach

4.1 Methodology

A CBA is used in this RIS to assess the real costs and benefits of each of the options incrementally to the Base Case. Where possible, costs and benefits that are quantified are assessed in an economic model by estimating each cost and benefit over a 10-year timeframe commencing 2022-23 (FY23). Costs and benefits are discounted over the 10-year modelling period to FY23 using a real discount rate of 4% p.a.

The aggregated costs and benefits are expressed using two key metrics: NPV and BCR. The NPV is calculated by subtracting the present value of costs from the present value of benefits. It measures the net benefit (or cost) to society of implementing the policy in monetary terms.

The BCR is calculated by dividing the present value of benefits by the present value of costs. If a project has a BCR greater than 1.0, the project is expected to deliver a positive NPV to a firm and its investors. The option with the highest NPV is expected to deliver the highest scale of net benefits to society, whereas the option with the highest BCR provides the highest benefit per unit of cost.

There are some potential costs and benefits that cannot be assessed quantitatively due to limited information availability. These are discussed in section 4.6.6.

4.2 Quantified costs and benefits

The costs and benefits quantified in this analysis are outlined in Table 8 and Table 9.

Table 8 Description of costs

Costs	Description of cost	Stakeholder	Section
Software amendment costs	The once-off cost incurred by DH to amend the SafeScript software to accommodate the proposed new medicines, excluding all other government implementation costs.	Government	Section 4.5.1
Stakeholder communication costs	The once-off stakeholder communication cost to government about the changes	Government	Section 4.5.2
Extra system maintenance	Any additional ongoing costs incurred by DH to maintain SafeScript as a result of including the proposed new medicines.	Government	Section 4.5.3

Costs	Description of cost	Stakeholder	Section
Government monitoring and enforcement costs	The ongoing costs incurred by DH to monitor and enforce compliance with the proposed regulations.	Government	Section 4.5.4
Cost of learning about change for prescribers and pharmacists	The once-off cost for prescribers and pharmacists to learn about the changes to SafeScript. This will include learning about the addition of the proposed new medicines to SafeScript and relevant information about the new medicines that have been added.	Industry	Section 4.5.5
Compliance costs	The ongoing costs of time to prescribers to check SafeScript prior to issuing a prescription for any of the proposed new medicines and the cost to pharmacists to check SafeScript prior to dispensing any of the new medicines.	Industry	Section 4.5.6
Extra time for people to obtain prescriptions	The ongoing costs of time to people waiting for a prescription to be checked by a medical practitioner or pharmacist.	Victorian community	Section 4.5.7
Treatment costs (for treatment of dependency)	The costs incurred to treat those identified via the SafeScript check as being at risk of harm, either through AOD programs or through appropriate primary care. This is an intervention in addition to the decision made by a medical practitioner not to issue a prescription.	Victorian community and/or government (depending on whether privately or publicly funded)	Section 4.5.8

Table 9 Description of benefits

Benefits	Description of benefit	Stakeholder	Section
Lives saved by SafeScript	Value of lives saved by SafeScript as prescribers. Value can be quantified by multiplying the number of avoided deaths by the value of statistical life.	Victorian community	Detailed discussion in section 4.6.1

Benefits	Description of benefit	Stakeholder	Section
Reduced hospitalisations	Value of saved resources by reducing the number of patients that are admitted to hospital.	Government/Victorian community	Detailed discussion in section 4.6.2
Avoided emergency department presentations	Value of saved resources by reducing the number of patients that present to emergency departments.	Government/Victorian community	Detailed discussion in section 4.6.3
Avoided PBS costs	Value of PBS subsidy for prescriptions not supplied.	Commonwealth government	Detailed discussion in section 4.6.4

4.3 CBA results

Table 10 presents the results of the CBA with both options indicating positive NPVs and BCRs. Option 2 (which includes pregabalin, gabapentin and tramadol in SafeScript) is the overall preferred option with the highest positive NPV of $100.6 million over 10 years and BCR of 1.46 relative to the Base Case. Option 1 (which includes pregabalin and gabapentin in SafeScript) is also preferred to the Base Case, with a positive NPV of $37.7 million over 10 years and BCR of 1.24 relative to the Base Case.

These CBA results only include benefits that are quantified. There is a range of benefits likely to arise from the proposed changes that have not been quantified but will increase the net benefits achieved under both options. These include avoided doctor consultations, avoided ambulance trips, improved quality of life, avoided workplace costs and avoided social costs for those living with a person affected by misuse of the medicines being proposed (see discussion 4.4.4).

Table 10 NPV results

Costs	Option 1	Option 2
Once-off software amendment costs	$149	$149
Stakeholder communication costs	$4,013	$4,013
Once-off learning - prescribers and pharmacists	$986,790	$986,790
Government monitoring and enforcement costs	$47,809	$71,714
Compliance costs for prescribers and pharmacists	$73,388,485	$83,203,476
Extra time for patients to obtain prescriptions	$37,033,069	$40,442,040
Treatment costs	$43,459,648	$91,899,924
Total costs	**$154,919,963**	**$216,608,106**
Benefits		
Lives saved by SafeScript	$187,836,160	$309,362,084
Avoided emergency department presentations	$3,558,094	$5,860,104
Reduced hospitalisations	$1,228,430	$2,023,197
Total benefits	**$192,622,684**	**$317,245,386**
NPV	**$37,702,720**	**$100,637,279**
BCR	**1.24**	**1.46**

The key assumptions estimated in this analysis, which underpin the largest cost drivers, are:

- Compliance costs:
  - 1 minute for a prescriber or pharmacist to check SafeScript (note pharmacists need to check more prescriptions than prescribers because of the need to check repeat scripts).
- Extra time for patients to obtain prescriptions:
  - 1 minute for a patient to wait for each prescription to be checked by the prescriber and the pharmacist.
- Treatment costs (for treatment of dependency)[99]:
  - 80% of patients requesting inappropriate prescriptions receive treatment. The other 20% do not receive any treatment.
  - Of the 80% who receive treatment, 25% people are treated through an AOD program (higher cost intervention). The other 75% are treated through appropriate primary care (lower cost intervention).

The largest benefit by far in the cost-benefit analysis is the benefit of lives saved by SafeScript. It is assumed that the inclusion of the medicines in SafeScript reduces deaths by 5% under Options 1 and

[99] As noted in Table 2, this is the cost incurred to treat those identified via the SafeScript check as being at risk of harm, either through AOD programs or through appropriate primary care. This is an intervention in addition to the decision made by a medical practitioner not to issue a prescription.

2 compared to the Base Case. Based on this assumption here will be 77 avoided fatalities due to pregabalin and gabapentin over the period 2023 to 2032, and 47 avoided fatalities due to tramadol.

The benefit is estimated by multiplying avoided deaths by a statistical value of life of $4.96 million (present value FY23).

Results are highly sensitive to certain assumptions, in particular the assumed reduction in deaths as a result of the inclusion of the medicines in SafeScript. Results of sensitivity testing are provided in section 4.8.

4.4 Data and assumptions

This section outlines key data and assumptions used to quantify costs and benefits.

4.4.1.1 Inflation rate and discount rate

All costs and benefits in this analysis have been presented in 2022-23 values using the Victorian DTF Macroeconomic forecasts (2.5% p.a. inflation rate). Total costs and benefits are presented as the sum of costs over a ten-year modelling period and estimated in present value terms using a 4% discount rate.

4.4.1.2 Number of prescriptions

The projections of total number of prescriptions[100], including the estimated split between the number of prescriptions supplied and number of inappropriate prescriptions[101], underpin the calculation of estimated costs and benefits.

This RIS uses historical trends in prescribing the three individual medicines to develop projections for the number of prescriptions supplied for the three medicines under the Base Case. The historical data used is PBS prescription data reported in the 2021 Austin Health review (see Appendix B of this RIS for historical data table).[102] Using this data, a constant annual growth rate in the number of prescriptions for each medicine is calculated for FY17-FY20[103]. This growth rate is then projected forward to forecast the number of prescriptions supplied per annum for each medicine under the Base Case for the forecast period FY23-FY32.

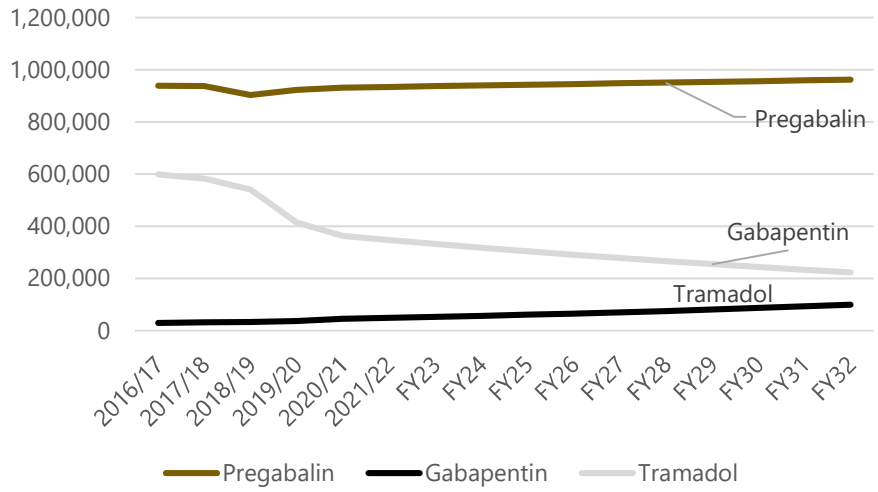
Due to data limitations, we have assumed the number of prescriptions obtained privately (i.e., not included in PBS data) is zero. In practice DH is aware of some private prescriptions being supplied for these medications but is unable to quantify this. The number of prescriptions estimated will therefore

[100] Defined as the sum of both the number of prescriptions supplied under the options and inappropriate prescriptions.
[101] Note: in this analysis the term 'number of inappropriate prescriptions' should be interpreted as the number of inappropriate prescriptions that are detected by medical practitioners and nurse practitioners and hence not supplied.
[102] 2021 Austin Health review, Appendix 2.
[103] This period excludes both the earlier period of steep increases in pregabalin and gabapentin prescriptions that have recently levelled off, and the large decrease in the final data year in tramadol prescriptions that is unusual compared with the long-term trend – reasons for this decrease are not known but could be due to the impacts of Covid and lockdowns in the latter half of 2019-20, although this is not certain.

be lower than what is actually the case, although as private prescriptions are believed to represent a small component of total prescriptions this is not considered a significant limitation of the analysis.

The number of prescriptions forecast to be supplied for the three medicines is shown in Figure 9.

Figure 9 Historical number of prescriptions and forecast number of forecast prescriptions for pregabalin, gabapentin and tramadol (2016/17-FY32)



To estimate the cost impacts under Options 1 and 2, the number of inappropriate prescriptions needs to be estimated.[104] Inappropriate prescriptions are defined in this RIS as prescriptions supplied in excess of therapeutic need. The proportion of prescriptions is estimated at 6.37%.[105] It is assumed that, under Options 1 and 2, half of the 6.37% are detected and identified as inappropriate through the introduction of SafeScript i.e. 3.19% of prescriptions supplied. The other half remain undetected and are assumed to be supplied.

Table 11 shows the number of prescriptions forecast for the three medicines under the Base Case, as well as the number that will be identified as inappropriate and not supplied under Options 1 and 2, and those prescriptions supplied as not identified as inappropriate. Over the forecast period FY23-FY32 there will be a total of 299,602 prescriptions of pregabalin and 18,948 prescriptions of gabapentin not supplied under Options 1 and 2 and a total of 99,789 prescriptions of tramadol not supplied under Option 2 (that would have otherwise been supplied under the Base Case).

[104] The number of inappropriate prescriptions influences two costs: compliance costs (which don't exist under the Base Case) and treatment costs. The CBA only considers incremental costs and benefits relative to the Base Case. Under the Base Case there is some treatment costs incurred because of measures other than the introduction of SafeScript, which will continue to be incurred under the Base Case and Options 1 and 2. This component of treatment costs is however not considered in the CBA as it is not incremental to the Base Case. Under Options 1 and 2 it is expected that there will be additional treatment costs as practitioners are able to identify people at risk of harm from obtaining prescriptions beyond therapeutic need and then recommend interventions. This intervention leads to both benefits and costs.

[105] Estimate is based on 986 Victorians being identified as obtaining high-risk medicines at levels beyond therapeutic need in FY12 x 100 prescriptions per person to meet the MBS criteria for beyond therapeutic need divided by 1.519 million S8 prescriptions in FY12= 6.37%. This estimation is sourced from the 2018 RIS (Appendix A). Whilst this estimate relates to S8 medicines, this is the best-known estimate available.

Table 11 Number of prescriptions, by type ('000)

	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	Total
Number of PBS prescriptions supplied under the Base Case ('000)											
Pregabalin	928	931	934	937	939	942	945	948	950	953	**9,407**
Gabapentin	42	45	49	52	56	60	65	70	75	81	**595**
Tramadol	379	363	347	332	318	304	291	278	266	255	**3,133**
Number of PBS prescriptions – inappropriate (based on detection by SafeScript) and not supplied under Options 1 and 2 ('000)											
Pregabalin	30	30	30	30	30	30	30	30	30	30	**300**
Gabapentin	1	1	2	2	2	2	2	2	2	3	**19**
Tramadol	12	12	11	11	10	10	9	9	8	8	**100**
Number of PBS Prescriptions supplied under Options 1 and 2 (not identified as inappropriate) ('000)											
Pregabalin	899	901	904	907	909	912	915	917	920	923	**9,107**
Gabapentin	41	44	47	51	54	58	63	68	73	78	**576**
Tramadol	367	351	336	322	308	294	282	269	258	246	**3,033**

4.5 Detailed cost analysis

This section estimates the costs included in the CBA.

4.5.1 Software amendment costs

Software amendment costs are once-off costs estimated as per the methodology and assumptions in Table 12. This is the cost of DH informing its external software service provider of the proposed change required, the service provider making the change (at zero additional cost under the service provider contract[106]) and DH then checking that the change made is correct. These activities are costed in the table below.

Software amendment costs are a minor cost and do not drive the CBA results.

[106] Information from the Department's current service provider.

Table 12 Software amendment costs

Cost incurred	Option	Hours required[107]	Cost of time (incl. loading)[108]	Total cost FY23-FY32 (not discounted)
DH advises SafeScript service provider to add proposed medicines	Options 1 & 2	0.5 hour at VPS 6 rate	$98.67 per hour[109]	$49.34
DH checks that the change is made and correct	Options 1 & 2	1.5 hour at VPS 4	$66.40 per hour	$99.60
Total software amendment costs (FY23-32 in PV terms) - Option 1				**$148.94**
Total software amendment costs (FY23-32 in PV terms) - Option 2				**$148.94**

Source: data and assumptions provided by DH.

4.5.2 Stakeholder communication costs

Stakeholder communication costs are once-off costs estimated as per the methodology and assumptions in Table 13. The implementation costs are assumed to be the same across Option 1 and Option 2 for simplicity purposes, however in practice costs might be slightly lower under Option 1 than Option 2 because only two medicines are being implemented. This is considered negligible and not accounted for. Overall stakeholder communication costs are small once-off costs and are minor relative to other costs incurred hence, they do not drive the CBA results.

Table 13 Stakeholder communication costs

Cost incurred	Option	Hours required[110]	Cost of time (incl. loading)[111]	Total cost FY23-FY32 (not discounted)
DH prepares message communicating change	Options 1 & 2	2 hours at VPS 5 rate	$77.84 per hour[112]	$155.68
DH checks message communicating change	Options 1 & 2	1 hour at VPS 6	$98.67 per hour	$98.67

[107] DH cost estimates.
[108] All VPS rates supplied by DH for FY23.
[109] All VPS rates supplied by DH for FY23. Includes 75% loading for overheads and on-costs as per Victorian Department of Treasury and Finance's *Conducting a regulatory change measurement Guide to assessing and calculating costs Toolkit 2 (*Version 1.1, March 2010).
[110] DH cost estimates
[111] All VPS rates supplied by DH for FY23
[112] All VPS rates supplied by DH for FY23. Includes 75 per cent loading for oncosts and overheads.

Cost incurred	Option	Hours required[110]	Cost of time (incl. loading)[111]	Total cost FY23-FY32 (not discounted)
DH to send message communicating change	Options 1 & 2	12 hours at VPS 5	$77.84 per hour	$934.08
DH to check message received	Options 1 & 2	4 hours at VPS 5	$77.84 per hour	$311.36
DH to update SafeScript website and key documents	Options 1 & 2	10 hours at VPS 5	$77.84 per hour	$778.40
DH updates practitioner and pharmacist on-line training	Options 1 & 2	8 hours at VPS 6	$98.67 per hour	$789.36
Advising stakeholder organisations by email -Preparing and checking email - sending email	Options 1 & 2	8 hours at VPS 6 + 2 hours at VPS 5	$98.67 per hour, VPS6 $77.84 per hour, VPS5	$945.04
Total stakeholder communication costs (FY23-32 in PV terms) - Option 1				**$4,013**
Total stakeholder communication costs (FY23-32 in PV terms) - Option 2				**$4,013**

Source: data and assumptions provided by DH.

4.5.3 Extra system maintenance

DH has been advised by its external service provider that the addition of either two or three extra medicines on SafeScript will not change the ongoing maintenance costs for SafeScript. As such, the incremental costs under Option 1 and Option 2 are zero.

4.5.4 Government monitoring and enforcement costs

Ongoing monitoring and enforcement costs are estimated as per the methodology and assumptions in Table 14.

Monitoring and enforcement costs are assumed to be linear relative to the number of medicines added to SafeScript.[113] As such, the monitoring and enforcement costs of Option 1 are assumed to be two-thirds of those incurred under Option 2. Together, government implementation, monitoring and enforcement costs account for just 0.1% of total present value of costs over 10 years.

Table 14 Government monitoring and enforcement costs

Cost incurred	Option	Hours required	Cost of time (incl. loading)	Total cost FY23-FY32 (not discounted)

[113] Efficiency gains, if any, are expected to be negligible and therefore not estimated.

DH to undertake extra monitoring in first year	Option 1	13.33 business days or 101.33 hours at VPS 5[114]	$77.84 per hour[115]	$12,620.46
DH to undertake extra monitoring in first year	Option 2	20 business days or 152 hours at VPS 5[116]	$77.84 per hour	$18,930.69
DH to undertake routine monitoring p.a. (ongoing)	Option 1	2/3 x 0.05FTE x 48 weeks per year x 5 days per year x 7.6 hours per day=60.80 hours p.a. at VPS 5[117]	$77.84 per hour	$55,215
DH to undertake routine monitoring p.a. (ongoing)	Option 2	0.05FTE x 48 weeks per year x 5 days per year x 7.6 hours per day=91.20 hours p.a. at VPS 5[118]	$77.84 per hour	$70,990.08
Total government monitoring costs (FY23-32 in PV terms) - Option 1				**$47,809**
Total government monitoring costs (FY23-32 in PV terms) - Option 2				**$71,714**

Source: data and assumptions provided by DH.

4.5.5 Cost of learning about change for prescribers and pharmacists

Learning costs are a once-off time cost incurred by prescribers (registered medical practitioners and nurse practitioners) and pharmacists to undertake the training created by DH, as outlined in Table 15. This training is specific to the addition of the new medicines to SafeScript.

It is assumed that all medical practitioners and pharmacists practising in Victoria undertake the training developed by DH as checking SafeScript is a mandatory part of their role should they prescribe or dispense the proposed medications. It is assumed that this training pertaining to the new medicines will take up to 30 minutes to complete.[119] Training time is not expected to materially differ between Options 1 and 2, hence the same estimate is used for both options.

[114] Assumed to be two-thirds of DH's cost estimates
[115] All VPS rates supplied by DH for FY23. Includes 75 per cent loading.
[116] DH cost estimates
[117] Assumed to be two-thirds of DH's cost estimates
[118] DH cost estimates
[119] Sapere assumption.

Table 15 Learning costs for prescribers and pharmacists

Cost incurred	Option	Hours required	Cost of time (incl. loading)	Total cost FY23-FY32 (not discounted)
Training for prescribers	Options 1 & 2	0.5 hour each[120] x 9,662 general practitioners in Vic.[121]	$159.00 per hour which includes loading[122]	$768,129
Training for pharmacists	Options 1 & 2	0.5 hour each x 6,977 pharmacists in Vic.[123]	Average $35.82 per hour[124] x (1+75% loading) = $62.68 per hour	$218,661
Total training costs (FY23-32 in PV terms) - Option 1				**$986,790**
Total training costs (FY23-32 in PV terms) - Option 2				**$986,790**

4.5.6 Compliance costs

Compliance costs are ongoing costs incurred by medical practitioners, nurse practitioners and dispensing pharmacists to check SafeScript before prescribing or dispensing the proposed new medicines. It is assumed that each check takes one minute. Modelling accounts for repeat prescriptions, where the pharmacist would be expected to check prescriptions more often than the medical practitioner or nurse practitioner. Medical practitioners and nurse practitioners must check SafeScript before prescribing the medicine (with repeat prescriptions supplied at a single visit requiring only one check) while pharmacists must check SafeScript before supplying a medicine (i.e., even if the prescription is a repeat). The number of checks undertaken by pharmacists is therefore higher than the number undertaken by medical practitioners. Where a prescription is not supplied, a pharmacist does not check SafeScript since no medicine will be supplied as no prescription has been presented.

It is noted that the information available on SafeScript makes it easier for prescribers to identify patients obtaining supplies of medicines beyond therapeutic need, thus potentially reducing the need for medical practitioners and pharmacists to have to use other methods to gather information to inform their decisions about issuing or dispensing a script. This could offset the checking time required (as the information available via the SafeScript check substitutes other methods for obtaining the

[120] Deloitte, *Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.*

[121] Australian Government Department of Health and Aged Care, *General Practice Workforce providing Primary Care services in Australia, September 2022*

[122] MBS Online reports benefit for Item 23 which is for a GP appointment of less than 20 min, and it is assumed that 4 appointments are conducted per hour. This is consistent with Deloitte, *Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.*

[123] Australian Government Department of Health and Aged Care, *Summary Statistics, State, October 2021*

[124] Fair Work Ombudsman, (2022, July 1). *Pay Guide - Pharmacy Industry Award [MA000012]*

information), however the size of this impact is uncertain so it has not been factored into cost estimates.

Compliance costs are estimated using the methodology and assumptions set out in Table 16.

Compliance costs are a significant driver of costs, accounting for around half of the total costs incurred under both Options 1 and 2.

Table 16 Compliance costs

Cost incurred	Option	Time required	No. prescriptions FY23-FY32	Cost of time (incl. loading)	Total cost FY23-FY32 (not discounted)
Cost to medical practitioners and nurse practitioners to check SafeScript	Option 1	1 minute per script[125], 1 check per script	Pregabalin: 9,406,662 Gabapentin: 594,907	$159.00 per hour including loading[126]	$26,504,160
	Option 2	1 minute per script, 1 check per script	Pregabalin: 9,406,662 Gabapentin: 594,907 Tramadol: 3,133,085	$159.00 per hour including loading	$34,806,835
Cost to pharmacists to check SafeScript – supplied prescriptions only[127]	Option 1	1 minute per script, 6 checks for pregabalin and gabapentin prescriptions[128]	Pregabalin: 9,107,060 Gabapentin: 575,960	Average $35.82 per hour[129] x (1+75%[130] loading) = $62.68 per hour	$60,693,773
	Option 2	1 minute per script, 1 check per tramadol	Pregabalin: 9,107,060	Average $35.82 per hour x	$63,862,588

[125] DH estimates 1 minute per check based on advice from industry.

[126] MBS Online reports benefit for Item 23 which is for a GP appointment of less than 20 min, and it is assumed that 4 appointments are conducted per hour. This is consistent with Deloitte, *Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.*

[127] See discussion of prescription numbers in section 4.4.1.2. Supplied prescriptions is the assumed 3.19% of the Base Case total number of prescriptions supplied.

[128] Note: PBS indicates maximum of one pack with 56 units and five repeats for pregabalin. Similarly, PBS notes maximum of one pack with 100 units and five repeats for gabapentin. A pharmacist would need to check the original script and each repeat on SafeScript prior to dispensing the medicines. An assumption of up to six checks per pregabalin or gabapentin script is therefore used.

[129] Fair Work Ombudsman, (2022, July 1). *Pay Guide - Pharmacy Industry Award [MA000012]*

[130] Based on DTF's guide to assessing costs

Cost incurred	Option	Time required	No. prescriptions FY23-FY32	Cost of time (incl. loading)	Total cost FY23-FY32 (not discounted)
		script[131], 6 checks for pregabalin and gabapentin scripts	Gabapentin: 575,960 Tramadol: 3,033,296	(1+75% loading) = $62.68 per hour	
Total compliance costs (FY23-32 in PV terms) - Option 1					**$73,388,485**
Total compliance costs (FY23-32 in PV terms) - Option 2					**$83,203,476**

4.5.7 Extra time for people to obtain prescriptions

This is the ongoing costs of time to people waiting for a prescription to be checked by a medical practitioner, nurse practitioner or pharmacist. All assumptions with respect to number of prescriptions and length of time checking are the same as those in the estimation of compliance costs in section 4.5.6. It is likely that this time may be offset as the patient needs to have fewer conversations with the medical practitioner or pharmacist about the medicines being supplied (as the information available via the SafeScript check substitutes this need), so this cost estimation might be higher than what actually occurs in practice.

Table 17 Cost of extra time to obtain prescription

Cost incurred	Option	Time required	No. prescriptions FY23-FY32	Cost of time	Total cost FY23-FY32 (not discounted)
Cost to wait for medical practitioners or nurse practitioners to check SafeScript	Option 1	1 minute per script[132], 1 check per script	Pregabalin: 9,406,662 Gabapentin: 594,907	$38.77 per hour[133]	$6,462,358
	Option 2	1 minute per script, 1 check per script	Pregabalin: 9,406,662 Gabapentin: 594,907 Tramadol: 3,133,085	$38.77 per hour	$8,486,752

[131] Note: PBS indicates maximum of one pack with 20 units and no repeats for tramadol. A pharmacist would need to check the original script and each repeat on SafeScript prior to dispensing the medicines.
[132] DH estimates 1 minute per check based on advice from industry.
[133] Value of leisure time per hour as per OBPR Regulatory Burden Measurement Framework, March 2020. Inflated to 2023 value.

Cost incurred	Option	Time required	No. prescriptions FY23-FY32	Cost of time	Total cost FY23-FY32 (not discounted)
Cost to wait for pharmacists to check SafeScript – supplied prescriptions only	Option 1	1 minute per script, 6 checks for pregabalin and gabapentin prescriptions[134]	Pregabalin: 9,107,060 Gabapentin: 575,960	$38.77 per hour	$37,539,192
	Option 2	1 minute per script, 1 check per tramadol script[135], 6 checks for pregabalin and gabapentin prescriptions	Pregabalin: 9,107,060 Gabapentin: 575,960 Tramadol: 3,033,296	$38.77 per hour	$39,499,109
Total compliance costs (FY23-32 in PV terms) - Option 1					**$37,033,069**
Total compliance costs (FY23-32 in PV terms) - Option 2					**$40,442,040**

4.5.8 Treatment costs

Alongside compliance costs, ongoing treatment costs are the most significant cost incurred in the analysis. Under Options 1 and 2 it is expected that there will be additional treatment costs as practitioners are able to identify people at risk of harm from obtaining prescriptions beyond therapeutic need and recommend interventions. The costs of treatment interventions are additional to the Base Case because they specifically arise from the detection of inappropriate prescriptions using SafeScript under Options 1 and 2.

Our analysis assumes that 80 per cent of patients requesting inappropriate prescriptions receive intervention treatment.[136] The other 20 per cent do not receive any intervention treatment. [137] People who receive intervention treatment are treated through either an AOD program (higher cost intervention) or through appropriate primary care[138] (lower cost intervention). Assumptions underpinning treatment costs are outlined in Table 18. The key assumption is that of the 80 per cent

[134] Note: PBS indicates maximum of one pack with 56 units and five repeats for pregabalin. Similarly, PBS notes maximum of one pack with 100 units and five repeats for gabapentin. A pharmacist would need to check the original script and each repeat on SafeScript prior to dispensing the medicines. An assumption of up to six checks per pregabalin or gabapentin script is therefore used.

[135] Note: PBS indicates maximum of one pack with 20 units and no repeats for tramadol. A pharmacist would need to check the original script and each repeat on SafeScript prior to dispensing the medicines.

[136] This is a Sapere assumption. There is no evidence available to support this assumption but it seems reasonable to assume some people will not receive treatment.

[137] In addition to care received from the medical practitioner within their medical appointment.

[138] Primary care often refers to medical care provided by general practitioners.

of patients requesting inappropriate prescriptions, 25 per cent[139] of patients receive treatment through AOD services at a cost of $5,334 per person and the remaining 75 per cent receive primary care treatment from a GP at a cost of $113 per person.

Table 18 Treatment costs

Cost incurred	Option	Treatment option (AOD or primary care)	No. inappropriate users needing treatment FY23-FY32	Cost of treatment	Total cost FY23-FY32 (not discounted)
No treatment	Option 1&2	20% of identified inappropriate users	n/a	n/a	$0
Cost to treat through AOD services – pregabalin and gabapentin	Option 1 & 2	25% of those who receive treatment[140]	Gabapentin and pregabalin: 318,550 inappropriate prescriptions between FY23-32 (see Table 11) divide by each user obtaining more than 6 individual prescriptions[141] (i.e., 7 each) x 80%[142] of which receive treatment= 36,406 people. 25% treated through AOD services = 9,101 people	$4,599.19 [143] per person in FY17 inflated to $5,333.65 per person in FY23	$48,543,838
Cost to treat through AOD services – tramadol	Option 2 only (in addition to line above)	25% of identified inappropriate users x 80% who receive treatment	Tramadol: 99,789 inappropriate prescriptions between FY23-32 divide by each user obtaining more than 1 individual script[144] (i.e., 2 each) = 49,894 people requiring treatment x 80% receive treatment = 39,916 people 25% treated through AOD services = 9,979 people	$5,333.65 per person in FY23	$53,223,833

[139] Based on the *New Horizons: The review of alcohol and other drug treatment services in Australia* report by National Drug and Alcohol Research Centre in 2014 which estimated that approximately 25% of people with substance use disorders accessed AOD services. Sapere assumes the remainder of people are treated through primary care.
[140] Ibid.
[141] Note: PBS indicates maximum of one pack with 56 units and five repeats for pregabalin, which is equivalent to a maximum of six individual prescriptions of single packs with 56 units and zero repeats on each script. Similarly, PBS notes maximum of one pack with 100 units and five repeats for gabapentin, which is equivalent to a maximum of six individual prescriptions of single packs with 100 units and zero repeats on each script.
[142] Sapere assumption
[143] This assumption is as per 2018 RIS. It is used because of lack of data to support otherwise.
[144] Note: PBS indicates maximum of one pack with 20 units and no repeats for tramadol therefore only one check required

Cost incurred	Option	Treatment option (AOD or primary care)	No. inappropriate users needing treatment FY23-FY32	Cost of treatment	Total cost FY23-FY32 (not discounted)
Cost to treat through primary care – pregabalin & gabapentin	Option 1 & 2	75% of identified inappropriate users[145] x 80% who receive treatment	Gabapentin and pregabalin inappropriate users that receive treatment = 36,406 people. 75% treated through primary care = $27,304 people	$113.30 per person in FY23[146]	$3,093,576
Cost to treat through primary care - tramadol	Option 2 only (in addition to line above)	75% of identified inappropriate users x 80% who receive treatment	Tramadol inappropriate users that receive treatment = 39,916 people 75% treated through primary care = 29,937 people	$113.30 per person in FY23	$3,391,820
Total treatment costs (FY23-32 in PV terms) - Option 1					**$43,459,648**
Total treatment costs (FY23-32 in PV terms) – Option 2					**$91,899,924**

Overall, 36,406 people receive treatment for pregabalin and gabapentin over the modelling period which results in 112 lives saved (see section 4.1.2.3), or alternatively that 323 people obtain treatment for every avoided gabapentinoid fatality. Similarly, for tramadol 39,916 people receive treatment over ten-years which results in 73 lives saved meaning that 546 people receive treatment for every avoided tramadol fatality. These ratios between treatment costs and avoided fatalities appear reasonable to us.

4.5.9 Total quantified costs

Total quantified costs for Options 1 and 2 are shown in Table 19. Total costs of Option 2 are $216.6 million (FY23 present values). This includes treatment costs $91.9 million (42%), compliance costs $83.2 million (38%) and extra time for patients to obtain prescriptions (19%).

Total quantified costs are lower under Option 1 totalling $154.9 million (FY23 present value). This includes compliance costs $73.4 million (47%), treatment costs $43.5 million (28%) and extra time for patients to obtain prescriptions $37 million (24%).

[145] Based on the *New Horizons: The review of alcohol and other drug treatment services in Australia* report by National Drug and Alcohol Research Centre in 2014 which estimated that approximately 25% of people with substance use disorders accessed AOD services. Sapere assumes the remainder of people are treated through primary care.
[146] MBS online item 44.

Table 19 Total quantified costs (PV 2023)

Costs	Option 1 (Pregabalin and gabapentin)	Option 2 (Pregabalin, gabapentin and tramadol)
Once-off software amendment costs	$149	$149
Stakeholder communication costs	$4,013	$4,013
Once-off learning - prescribers and pharmacists	$986,790	$986,790
Government monitoring and enforcement costs	$47,809	$71,714
Compliance costs - prescribers and pharmacists	$73,388,485	$83,203,476
Extra time for patients to obtain prescriptions	$37,033,069	$40,442,040
Treatment costs	$43,459,648	$91,899,924
Total costs	**$154,919,963**	**$216,608,106**

4.6 Detailed benefits analysis

4.6.1 Lives saved by SafeScript

The largest benefit in the CBA is the benefit of lives saved by SafeScript. This benefit is estimated by multiplying the number of avoided fatalities (see section 4.1.2.3) by a statistical value of life of $4.2 million in FY14, which is inflated to $4.96 million in FY23.[147]

The results of the analysis are very sensitive to the assumption for the number of lives saved as a result of including the medicines in SafeScript. We first need to forecast the number of deaths in Victoria due to pregabalin, gabapentin and tramadol under the Base Case. This is estimated by applying the fatal toxicity index (FTI, fatalities per million prescriptions) to the projected number of prescriptions (see discussion of FTI in section 2.2.2). This analysis only uses unique deaths rather than where multiple drugs (including pregabalin, gabapentin or tramadol) contributed to a death. Forecast deaths from overdoses involving a combination of drugs including the three medicines are higher than just those involving the three medicines as unique contributors, which indicates the forecast of deaths is likely on the low side.[148] However, it is more difficult to forecast the impact of including individual medicines on SafeScript on deaths involving a combination of drugs (e.g. extent to which removing one medicine from a group of medicines) so for simplicity[149] this RIS uses only unique deaths to estimate forecast deaths.

Table 20 shows the forecast number of deaths under the Base Case for the period FY23-FY32.

Table 20 Forecast deaths in Victoria under the Base Case

	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32
Pregabalin	67.3	71.3	75.4	79.8	84.5	89.4	94.7	100.2	106.0	112.2
Gabapentin	3.1	3.5	3.9	4.5	5.1	5.7	6.5	7.4	8.4	9.5
Tramadol	44.4	47.4	50.6	54.1	57.8	61.7	66.0	70.5	75.3	80.4

It is assumed that the inclusion of the medicines in SafeScript reduces deaths by 5% under Options 1 and 2 compared to the Base Case. This is a Sapere assumption and has some uncertainty attached to it, but is based on the following:

- there has been a declining trend in overdose deaths involving pharmaceutical drugs monitored under SafeScript since 2018 which coincides with SafeScript's introduction - overdose deaths for monitored drugs decreased by about 5% from 2018 to 2021 (see discussion in section 1.3.2 and Figure 1)

[147] Office of Best Practice Regulation, 2014. $4,961,000 is $4,200,000 in 2014 dollars inflated to FY23 dollars. This is the standard value used for cost-benefit analyses in Australia.
[148] Using the FTI for overdoses where the three medicines are contributing drugs.
[149] And reflecting principle of proportionality as per Victorian Guide of Regulation, p.5.

- following the introduction of RTPM in Tasmania, the state experienced a 5% reduction in the number of deaths.[150]

This assumption is significantly lower than the 12% reduction assumed in the 2018 RIS, which took into account the Tasmanian evidence but based its assumption on evidence from the United States which showed state-based mandatory prescription monitoring systems have reduced deaths by 12%[151] [152]. The rationale provided for using the US evidence was that the Tasmanian system was voluntary and therefore its effectiveness was expected to be less in comparison to jurisdictions where use of the system is mandatory[153]. It is noted that, given each avoided fatality is valued at almost $5 million, this assumption is the key driver of the outcome of the CBA and the results are very sensitive to it. This is demonstrated in the sensitivity analysis in section 4.7.

Significantly, rate of harm indicated by FTI trends have been increasing at very high rates for both pregabalin, gabapentin and tramadol in both unique and contributing circumstances.[154] Calculated over five years to 2020, the compound annual growth rate exceeded 10 percent except for pregabalin as a sole agent of harm with CAGR of 5.5 percent.[155] Consequently, the rate of growth of estimated avoided fatalities is higher than the rate of growth in prescriptions and increasing in Option 2 even as the volume of prescriptions decreases.

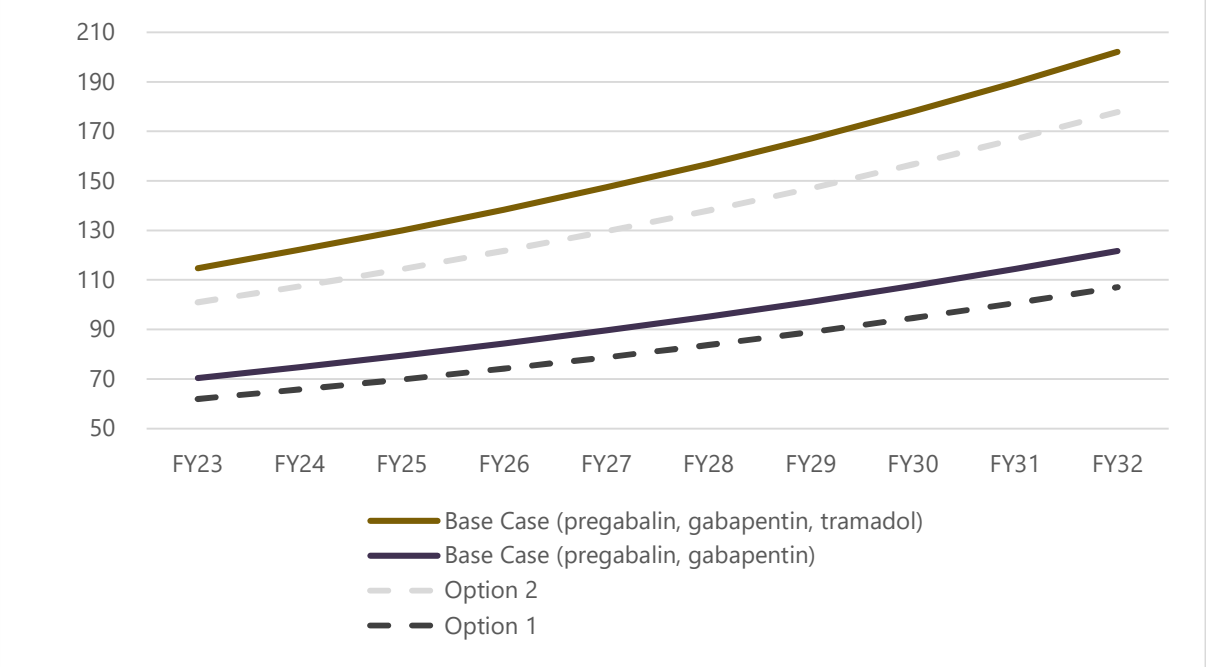
Table 21 shows projected deaths and projected avoided deaths under Options 1 and 2 versus the Base Case for FY23 to FY32. Projected deaths are also presented diagrammatically in Figure 10. Based on assumptions used for this RIS it is projected that there will be 77 avoided fatalities under Option 2 over the period 2023 to 2032 and 47 avoided fatalities under Option 1 (30 avoided deaths due to tramadol).

[150] 2018 RIS p.22. This is sourced in this RIS to Pharmaceutical Benefits Advisory Committee 2015 however we have been unable to find the original source document.
[151] See Dowell, D., Zhang, K., Noonan, R., & Hockenberry, J. (2016). Mandatory Provider Review And Pain Clinic Laws Reduce The Amounts Of Opioids Prescribed And Overdose Death Rates. Health Affairs, 35(10), 1876-1883. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/27702962.
[152] Noting these examples relate to a broader range of medicines included in the RPTM systems than just pregabalin, gabapentin and tramadol.
[153] See discussion of assumption on p.22 of the 2018 RIS.
[154] 2021 Austin Health review
[155] Sapere calculations from 2021 Austin Health review and Coroners Court of Victoria, Victorian overdose deaths, 2012-2021, 30 August 2022

Table 21 Projected deaths and avoided deaths under Base Case versus Options 1 and 2, 2023 to 2032

	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	Total
Projected deaths under the Base Case											
Pregabalin, gabapentin	70	75	79	84	90	95	101	108	114	122	**938**
Pregabalin, gabapentin, tramadol	115	122	130	138	147	157	167	178	190	202	**1,547**
Projected deaths under Options 1 and 2											
Option 1 (pregabalin, gabapentin)	67	71	75	80	85	90	96	102	109	116	**891**
Option 2 (pregabalin, gabapentin, tramadol)	109	116	124	131	140	149	159	169	180	192	**1,469**
Projected avoided deaths under Options 1 and 2											
Option 1	4	4	4	4	4	5	5	5	6	6	**47**
Option 2	6	6	7	7	7	8	8	9	9	10	**77**

Figure 10 Projected deaths, 2023 to 2032



A summary of the methodology for estimating the value of lives saved is provided in Table 22.

Table 22 Value of lives saved

Medicines	Option	Number of avoided fatalities	Value of statistical life	Total benefit FY23-FY32
Pregabalin and gabapentin	Options 1 & 2	47 avoided deaths between FY23-32, relative to the Base Case	$4,961,000 per avoided death[156]	$227,093,013
Tramadol	Option 2 only	30 avoided deaths between FY23-32, relative to the Base Case	$4,961,000 per avoided death	$147,169,608
Total avoided deaths - benefits (FY23-32 in PV terms) - Option 1				**$187,836,16**
Total avoided deaths - benefits (FY23-32 in PV terms) - Option 2				**$309,362,084**

4.6.2 Reduced hospitalisations

Inappropriate use of pregabalin, gabapentin or tramadol can lead to admission for treatment in hospital. Some admissions can be avoided by using SafeScript, providing benefits of avoided or reduced hospitalisations. Reduced hospitalisations' benefits are estimated using the assumptions below.

The number of avoided hospitalisations is estimated based on the number of avoided fatalities outlined in section 4.6.1. A fact sheet by the US Centers for Disease Control and Prevention (CDC) on the misuse or overdose on prescription pain killers found that for every overdose death from prescription pain killers, there are 10 hospitalised treatment admissions.[157] Using this as the basis for our assumption, the number of avoided fatalities is multiplied by 10 to estimate that there are 469 avoided hospitalisations due to pregabalin and gabapentin over the period 2023 to 2032, and 304 avoided hospitalisations due to tramadol.

The cost of a hospital admission is estimated at $9,168.19 using national efficient prices for relevant Australian Refined Diagnosis Related Groups (AR-DRGs) as published in the National Efficient Price Determination 2021–22 by the Independent Hospital Pricing Authority (IHPA). Price weights for the following AR-DRGs were applied to the National Efficient Price for 2021-22 of $5,597[158], with prices weights weighted equally across the five categories:

- V61A Drug Intoxication and Withdrawal, Major Complexity
- V61B Drug Intoxication and Withdrawal, Minor Complexity
- V63Z Opioid Use and Dependence
- V64A Other Drug Use and Dependence, Major Complexity

[156] Office of Best Practice Regulation, 2014. $4,961,000 is $4,200,000 in 2014 dollars inflated to FY23 dollars. This is the standard value used for cost-benefit analyses in Australia.
[157] Centers for Disease Control and Prevention. (n.d.). Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses
[158] The Independent Hospital Pricing Authority, *National Efficient Price Determination 2021–22*, 2 March 2021, p.7.

- V64B Other Drug Use and Dependence, Minor Complexity.[159]

The estimated cost, based on FY22 figures, was then inflated to FY23 using the percentage change in the NEP from FY22 to FY23[160], to estimate the cost of $9,168.19 for a hospital admission visit.

The methodology and assumptions are summarised in Table 23.

Table 23 Avoided hospital admissions

Medicine	Avoided deaths	Avoided hospital admissions	Cost of hospital admission	Total benefit FY23-FY32
Pregabalin and gabapentin	46.9 between FY23-FY32	46.9 avoided deaths x 10 per avoided death[161] = 469 avoided hospitalisations between FY23-FY32	$9,168.19 per admission	$4,301,719
Tramadol only	30 between FY23-FY32	30 avoided deaths x 10 per avoided death = 300 avoided hospitalisations between FY23-FY32	$9,168.19	$2,787,766
Total avoided hospital admissions benefits (FY23-32 in PV terms) - Option 1 (pregabalin and gabapentin)				$3,558,094
Total avoided hospital admissions benefits (FY23-32 in PV terms) - Option 2 (pregabalin, gabapentin and tramadol)				$5,860,104

4.6.3 Avoided emergency department presentations

Similar to hospital admissions, inappropriate pregabalin, gabapentin or tramadol use can lead to emergency department presentations, some of which can be avoided through using SafeScript, providing benefits of avoided emergency department costs. Reduced or avoided hospital emergency presentations are estimated using the assumptions below.

Like avoided hospitalisations, the number of avoided emergency department presentations is estimated based on the number of avoided fatalities outlined in section 4.6.1. A fact sheet by the US Centers for Disease Control and Prevention (CDC) on the misuse or overdose on prescription pain killers found that for every overdose death from prescription pain killers, there are 32 emergency

[159] The Independent Hospital Pricing Authority, *National Efficient Price Determination 2021–22*, 2 March 2021. See Appendix H – Price weights for admitted acute patients – AR-DRG V10.0 in Price Weight Tables.

[160] NEP in FY23 is $5,797 as set out in the IHPA's *National Efficient Price Determination 2021–22*. The NEP and price weights for FY23 were not sourced from this report as price weights for this year they were incomplete for the AR-DRGs being considered. Instead the cost is estimated using the FY22 NEP and price weights and then inflated.

[161] Centers for Disease Control and Prevention. (n.d.). Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses

department visits for misuse or overdoses.[162] Therefore, it is estimated that there were 1,501 avoided emergency department presentations due to pregabalin and gabapentin over the period 2023 to 2032, and 973 due to tramadol.

The cost of an emergency department presentation is estimated to be $989.16.16. This cost is estimated by applying the price weights for a set of relevant Urgency Disposition Groups (UDGs) to the IHPA's National Efficient Price for 2022-23 of $5,797[163] [164]. UDGs are a standardised way to classify patients in EDs and group presentations according to type of visit, episode end status and triage. The relevant UDG codes used to estimate the cost are:

- Admitted Triage 2 – Toxic effect of drugs
- Admitted Triage 3 – Poisoning/Toxic effects of drugs
- Admitted Triage 4 – Poisoning/Toxic effects of drugs
- Non-Admitted Triage 2 – Alcohol/drug abuse.[165]

Table 24 summarises the calculation for benefit derived from avoided emergency department presentations.

Table 24 Avoided emergency department presentations

Medicine	Avoided deaths	Avoided emergency department presentations	Cost of emergency department presentation	Total benefit FY23-FY32
Pregabalin and gabapentin	46.9 between FY23-FY32	46.9 avoided deaths x 32 per avoided death[166] = 1,501 avoided emergency department presentations, relative to the Base Case between FY23-32	$989.16 per presentation[167]	$1,485,166
Tramadol	30 between FY23-FY32	30 avoided deaths x 32 per avoided death = 973 avoided emergency department presentations, relative to	$989.16 per admissions	$962,475

[162] Centers for Disease Control and Prevention. (n.d.). Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses.
[163] The Independent Hospital Pricing Authority, *National Efficient Price Determination 2021–22*, 2 March 2021, p.7.
[164] Each UDG has a price weight that is applied to the National Efficient Price for an emergency department presentation. The cost of an emergency department presentation for an overdose of one of the three medicines is estimated by calculating the average of the price weights for the UDGs used (assuming equal weightings) and multiplying by the National efficient Price.
[165] The Independent Hospital Pricing Authority, *National Efficient Price Determination 2021–22*, 2 March 2021. Appendix M – Price weights for emergency service patients – UDG V1.3.
[166] Centers for Disease Control and Prevention. (n.d.). Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses.
[167] Deloitte, *Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018*.

		the Base Case between FY23-32		
Total avoided ED presentations benefits (FY23-32 in PV terms) - Option 1 (pregabalin and gabapentin)				$1,228,430
Total avoided ED presentations benefits (FY23-32 in PV terms) - Option 2 (pregabalin, gabapentin and tramadol)				$2,023,197

4.6.4 Avoided PBS costs (to the Commonwealth)

Although not an objective of this RIS, SafeScript is expected to result in savings to the PBS as several prescriptions may not be supplied by the prescriber, which results in PBS savings for the Commonwealth Government. These savings are estimated by multiplying the number of inappropriate prescriptions (see section 4.4.1.2 by the PBS savings for each medication.[168]

It is noted that these benefits accrue to the Commonwealth PBS and unlikely to have direct effects on Victorians and are therefore not considered in the total quantified cost estimate (see section 4.6.5).

Table 25 Savings to the PBS

Medicine	Option	Number of prescriptions not supplied (inappropriate prescriptions)	PBS benefit payment per script	Total benefit FY23-FY32
Pregabalin and gabapentin	Options 1 & 2	318,550 prescriptions not supplied between FY23-32 (see section 4.1.2.2)	$19.04 per pregabalin script and $23.88 per gabapentin script[169]	$6,156,801 = $5,704,414 pregabalin + $452,387 gabapentin
Tramadol	Options 2	99,789 prescriptions not supplied between FY23-32 (see section 4.1.2.2)	$17.43 per tramadol script	$1,739,300
Total savings to the PBS benefits (FY23-32 in PV terms) - Option 1				**$5,180,154**
Total savings to the PBS benefits (FY23-32 in PV terms) - Option 2				**$6,668,297**

[168] Australian Government Services Australia. (2022). Pharmaceutical Benefits Schedule Item Reports
[169] Ibid.

4.6.5 Total quantified benefits

Total benefits are $228.4 million under Option 2 comprising saved lives benefits of $223.0 million (97.6%) and $5.4 million (2.4%) are avoided emergency department and hospital benefits in present value terms. Total benefits are lower under Option 1 totalling $134.9 million of which $131.7 million (97.6%) are saved lives benefits and $3.2 million (2.4%) are avoided emergency department and hospital benefits.

Table 26 Total benefits in present value[170]

Benefits	Option 1 (PV)	Option 2 (PV)
Lives saved by SafeScript	$187,836,160	$309,362,084
Avoided emergency department presentations	$3,558,094	$5,860,104
Reduced hospitalisations	$1,228,430	$2,023,197
Total benefits	**$192,622,684**	**$317,245,385**

4.6.6 Impacts not quantified

There is a range of benefits likely to arise from the proposed changes under both options that have not been quantified but will increase the net benefits achieved (benefits minus costs). These include avoided doctor consultations, avoided ambulance costs, improved quality of life, avoided workplace costs and avoided social costs for those living with a person affected by misuse of the medicines being proposed. These are discussed in turn in this section.

Avoided ambulance trips

With reduced hospitalisations and reduced emergency department presentations there is also likely to be reduced ambulance trips and costs of this. This has not been included in the quantified benefits above because of uncertainty around the cost of an ambulance trip and how many trips are taken, and this cost is not expected to be material to the overall findings. However, indicatively, for Option 1, if an ambulance trip was required for all hospital admissions and emergency department presentations (estimated total of 1,970 admissions and presentations per year for Option as set out in sections 4.6.2 and 4.6.3) at a cost of $1,600 per trip[171] this would be $3.1 million per year.

[170] Does not include avoided PBS costs as these benefits accrue to the Commonwealth PBS and unlikely to have direct effects on Victorians and are therefore not considered in the total quantified cost estimate (see discussion section 4.6.4).
[171] $1,500 is indicative estimate only based on average of Emergency Road Transport Fees of $1,306 for metropolitan and $1,927 for regional and rural (https://www.health.vic.gov.au/patient-care/ambulance-fees).

Improved quality of life

A person who is misusing or dependent on the three medicines may have a lower quality of life than would otherwise be the case. For extra-medical opioid use, Curtin University estimated this cost to be $14.9 billion in Australia in 2015-16, which is over 5 times the estimated cost for tangible costs of premature mortality, $2.6 billion.[172] This is clearly a significant cost, however it did not include this cost in the total social costs to society because:

> *'estimation of the cost of harms in social cost studies does not typically include the harms arising to the consumer because any harms from consumption will be factored into the purchasing decision along with the purchase price, so that the overall benefits outweigh the overall costs (and harms) of consumption.'*

On the other hand, Curtin University noted that:

> *'this model of rational consumption appears to be less well suited to the explanation of the consumption of substances with dependence potential, or more specifically in people who are identified as severely dependent on a substance.'*

This cost has not been estimated for this RIS given the complexity of the underlying cost calculation (see Curtin University report p.122), however it seems reasonable to say that improved quality of life is a potentially significant benefit that has not been quantified (potentially higher than other benefits quantified).

Avoided workplace costs

Misuse of pharmaceutical medicines can impact a person's workplace performance, productivity and safety. The National Drug Research Institute (NDRI) at Curtin University reviewed evidence for a range of harms associated with opioid misuse and illicit drug use and estimated costs to society of harms where possible. In relation to workplace costs, Curtin University noted that:

> *'extra-medical opioid use can pose a workplace risk. Use can impair psychomotor and cognitive functioning, weaken the immune system, impair driving ability, increase risk of fractures, and dysregulate mood (Chihuri and Li, 2017; Manchikanti et al., 2012). These effects can negatively affect workplace safety, performance and productivity…Opioid effects can last two to 72 hours…(Smith, 2009).'*[173]

Curtin University estimated workplace costs to comprise 8% of the total cost of opioid misuse and illicit drug use in 2015-16 that was estimated. This cost estimate might not be directly applicable to pregabalin, gabapentin and tramadol because of the different medicines assessed (including illicit

[172] A disability-adjusted life year (DALY) approach was used to estimate the quality-of-life impact.

[173] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16,* Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University, chapter 6.

drugs) but is an indicator of potential cost that could be avoided through inclusion of the three medicines in SafeScript.

Avoided traffic accidents

Legal and illegal substances can impair driving ability and as such are likely to increase the rate at which road traffic accidents occur, although there is less evidence relating to pharmaceutical medicines than for alcohol and illegal substances.[174] We also have no specific evidence that prescribing controls for these three medicines may result in a reduction in traffic accidents.

Costs to those living with a person affected by misuse of medicines

Curtin University notes that

> *'Affected family members…living with a person with extra-medical opioid dependence may experience intangible costs through reduced quality of life and may also incur tangible costs. Many of the issues impacting quality of life can be similar across different drug use disorders and may include: violence; emotional abuse; impaired mental wellbeing; increased ill-health; diminished family relationships; and, alienation from friends and the wider community (Orford, 2015; Orford et al., 2013). There may also be costs through lost wages in caring for the person with drug dependence and, in some cases theft from the household.'* [175]

Curtin University notes the challenges in estimating this cost.

Avoided criminal justice costs

Many studies include criminal justice costs as a cost of misuse of opioids or illegal drugs. We consider this less relevant to potential over-use of pregabalin, gabapentin and tramadol because these three medicines are typically sourced via a PBS script (including prescription shopping) rather than depending on crime to pay for the medicines. Similarly, it is possible there could be substitution away from pharmaceutical medicines towards illegal drugs, however we have no evidence to assess the likelihood of this occurring.

Avoided doctor consultations

SafeScript may result in fewer medical consultations if it deters people from visiting the doctor to request the medicines (if prescriptions are refused thus deterring people from visiting the doctor to obtain high-risk medicines beyond therapeutic need.). This could provide savings to the Medicare Benefits Schedule (MBS). This impact has not been quantified due to uncertainty about number of avoided doctor consultations. However, we consider it is not likely to be material to the result.

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[174] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16,* Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University, chapter 8.

[175] Ibid, chapter 9.

These benefits (if any) accrue to the Commonwealth MBS and are unlikely to have direct effects on Victoria. This parameter is therefore not considered in the cost-benefit analysis.

4.7 Preferred option

Based on the results of the CBA, the preferred option is Option 2: add pregabalin, gabapentin and tramadol to the medicines monitored in SafeScript (Option 1 plus tramadol).

Under the preferred option pregabalin, gabapentin and tramadol would be added to Schedule 5 Monitored poisons and Schedule 6 Monitored supply poisons of the Regulations.

4.8 Sensitivity testing

This section outlines key sensitivities. The key parameters are those relating to the projection of future prescriptions and deaths as these projections drive both the benefits and the variable costs, which are a significant share of costs. The sensitivity testing demonstrates the impact of varying two key assumptions regarding the impact of SafeScript as follows:

- Percentage of forecast deaths avoided is tested at high 7% and low 3% compared to the central assumption of 5% (see section 4.6.1 for discussion of central assumption). It is noted that the lower and upper bound estimates used for sensitivity testing are not evidence based and are used to illustrate the sensitivity of results to a change in the assumption.
- Percentage of inappropriate prescriptions that are not supplied is tested at low 30 percent and high 70 percent compared to the central estimate of 50% (see section 4.4.1.2 for discussion of the central assumption). A cost side sensitivity (not NPV sensitivity) is conducted for this parameter due to limitations of modelling and uncertainty about the impact on benefits[176].

Table 27 and Table 28 show the results of this sensitivity testing.

It can be seen that results are sensitive to the change in the assumption in regard to the percentage of deaths avoided. For Option 1 an increase in this assumption from 5% to 7% increases the BCR from the central estimate of 1.24 to 1.74. For Option 2 an increase in this assumption to 7% increases the BCR from the central estimate of 1.46 to 2.05. It is noted that a reduction in this assumption to 3% will result in a negative BCR of 0.75 for Option 1 and 0.88 for Option 2, although based on the evidence available (taking into account the Tasmanian evidence, the US evidence and the experience under SafeScript since 2018 as discussed in section 4.6.1) a reduction in deaths less than 5% is not considered likely to occur.

For the assumption in regard to the percentage of inappropriate prescriptions not supplied under SafeScript, the findings for costs do not change substantially under the high and low assumptions.

[176] The CBA model is not dynamic across costs and benefits.

4.8.1 Avoided deaths

Table 27 Sensitivity to parameter – Avoided deaths

Costs	Option 1- original	Option 1 - low	Option 1 - high	Option 2 - original	Option 2 - low	Option 2 - high
Parameter - Proportion of avoided fatalities	5%	3%	7%	5%	3%	7%
Once-off software amendment costs	$149	$149	$149	$149	$149	$149
Stakeholder communication	$4,013	$4,013	$4,013	$4,013	$4,013	$4,013
Once-off training for prescribers and pharmacists	$986,790	$986,790	$986,790	$986,790	$986,790	$986,790
Government monitoring and enforcement costs	$47,809	$47,809	$47,809	$71,714	$71,714	$71,714
Compliance costs	$73,388,485	$73,388,485	$73,388,485	$83,203,476	$83,203,476	$83,203,476
Extra time for patients to obtain prescriptions	$37,033,069	$37,033,069	$37,033,069	$40,442,040	$40,442,040	$40,442,040
Treatment costs	$43,459,648	$43,459,648	$43,459,648	$91,899,924	$91,899,924	$91,899,924
Total costs	**$154,919,963**	**$154,919,963**	**$154,919,963**	**$216,608,106**	**$216,608,106**	**$216,608,106**
Benefits						
Lives saved by SafeScript	$187,836,160	$112,701,696	$262,970,623	$309,362,084	$185,617,251	$433,106,918
Avoided emergency department presentations	$3,558,094	$2,134,857	$4,981,332	$5,860,104	$3,516,062	$8,204,146
Reduced hospitalisations	$1,228,430	$737,058	$1,719,802	$2,023,197	$1,213,918	$2,832,476
Total benefits	**$192,622,684**	**$115,573,610**	**$269,671,757**	**$317,245,386**	**$190,347,231**	**$444,143,540**
Net Present Value	**$37,702,720**	**-$39,346,353**	**$114,751,794**	**$100,637,279**	**-$26,260,875**	**$227,535,433**
BCR	**1.24**	**0.75**	**1.74**	**1.46**	**0.88**	**2.05**

Note: In reality we would expect an increase in fatalities to somewhat reduce the demand for treatment and subsequently reduce the treatment costs, however these reductions are expected to be small and not worth modelling.

4.8.2 Prescriptions

Table 28 Sensitivity to parameter - Proportion of inappropriate prescriptions: rejected by prescribers

Costs	Option 1- Original	Option 1- low	Option 1 - high	Option 2 - original	Option 2 - low	Option 2 - high
Parameter - Proportion of inappropriate prescriptions: detected by SafeScript	50%	30%	70%	50%	30%	70%
Once-off software amendment costs	$149	$149	$149	$149	$149	$149
Stakeholder communication	$4,013	$4,013	$4,013	$4,013	$4,013	$4,013
Once-off training for prescribers and pharmacists	$986,790	$986,790	$986,790	$986,790	$986,790	$986,790
Government monitoring and enforcement costs	$47,809	$47,809	$47,809	$71,714	$71,714	$71,714
Compliance costs	$73,388,485	$74,060,676	$72,716,294	$83,203,476	$83,911,345	$82,495,608
Extra time for patients to obtain prescriptions	$37,033,069	$37,448,820	$36,617,318	$40,442,040	$40,879,857	$40,004,222
Treatment costs	$43,459,648	$26,075,789	$60,843,508	$91,899,924	$55,139,955	$128,659,894
Total costs	**$154,919,963**	**$138,624,046**	**$171,215,881**	**$216,608,106**	**$180,993,823**	**$252,222,390**

4.9 Small business and competition impacts

This section assesses the small business and competition impacts of the preferred option.

4.9.1 Small business impacts

Small businesses may experience disproportionate effects from regulation for a range of reasons. This may include that the requirement applies mostly to small businesses, or because small businesses have limited resources to interpret compliance requirements or meet substantive compliance requirements compared to larger businesses.

As nearly all GP clinics (97 per cent) and a majority of pharmacies (56 per cent) in Victoria are considered small businesses, much of the impact of the proposed change to Regulations will be borne by small businesses (defined by the ATO as those with an annual turnover of less than $2 million).[177] There may be some costs in forgone revenue to pharmacies resulting from fewer prescriptions being issued but this is not expected to be material.

General practitioners, nurse practitioners and pharmacists in clinics and community pharmacies are already required to check SafeScript and therefore have well established IT systems and processes in place. There will be a small cost (30 minutes of time per practitioner and pharmacist) to learn about the changes.

As every general practitioner, nurse practitioner and pharmacist will need to learn about the new requirement and then do checks as needed for their patients, this is not expected to disproportionately impact small businesses.

4.9.2 Competition impacts

The Victorian Guide to Regulation also requires a RIS to assess the impact of regulations on competition. Regulations can affect competition by preventing or limiting the ability of businesses and individuals to enter and compete within particular markets.

To exist in the industry or enter into the industry currently, a business is required to have IT software that can interface with SafeScript. The proposed change to Regulations does not impose any additional IT system costs on businesses. The costs of learning about the changes are expected to be small and are not expected to have competition impacts.

The changes will have an impact on how many prescriptions of the three medicines are supplied, which will impact pharmaceutical manufacturers of the medicines (as fewer medicines will need to be manufactured) however this impact is very small (only a 3.19% reduction is forecast), representing an immaterial proportion of the total amount of medicines that these businesses manufacture.

[177] Australian Bureau of Statistics, *8165.0 Counts of Australian Businesses, including Entries and Exits*, June 2017 to June 2021, Businesses by Main State by Industry Class by Turnover Size Ranges, June 2021 (a) (b), (Data Cube 3).

5. Implementation, enforcement and evaluation

This chapter discusses key issues to be considered in the implementation, enforcement and evaluation of the Regulations.

5.1 Implementation

Because the proposed change only involves adding a small number of medicines to Schedule 5 and Schedule 6 in the existing Regulations, the work required to implement the changes is expected to be minimal.

DH will be responsible for overseeing all changes brought about by the implementation of proposed changes and for administering and monitoring compliance by health professionals to ensure they meet their legal obligations in using SafeScript appropriately.

DH are responsible for implementing and administering the SafeScript system. They have the regulatory understanding and technical skills to undertake implementation of any changes and ongoing administration of the system using existing policies and processes.

DH have a responsibility to identify and address industry compliance. The main steps in implementation are set out in Table 28.

Table 29 Implementation requirements

Implementation requirement	Task
Add medicines to SafeScript database	DH to request SafeScript Service Provider to add names of additional medicines to the monitored poisons field. SafeScript Service Provider makes the change, which is considered a simple task.
Communicate with practitioners and pharmacists to inform that new medicines have been added	DH to send message to all practitioners and pharmacists that the 3 medicines have been or are to be added as SafeScript monitored poisons, via the SafeScript system, and advise that learning module is available for SafeScript.
Communicate with key stakeholders and general public to inform that new medicines have been added	Update SafeScript website and any key public documents. Advise stakeholder organisations by email.
Provide learning and training materials for practitioners and pharmacists.	Update the SafeScript learning modules to reflect the addition of new medicines in SafeScript

5.2 Evaluation

This RIS proposes that the evaluation strategy for the proposed medicines comprises the following two elements which are in line with the evaluation strategy for SafeScript as proposed in the 2018 RIS (see chapter 6 of the 2018 RIS):

- Ongoing review
- Mid-term review.

Ongoing review
As part of the broader SafeScript evaluation strategy outlined in the 2018, DH is conducting ongoing monitoring of the effectiveness of SafeScript via the collection and analysis of a range of data on a frequent basis. The medicines included in SafeScript will be included in this ongoing monitoring. This includes reviewing externally collected data and evidence including the Australian Commission on Safety and Quality of Health Care's report *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21*[178] and evidence and recommendations provided in reports of the Coroners Court of Victoria.

Data from the SafeScript system will be used to support ongoing monitoring and review. A key step for DH is to review the requirements and processes for collecting this data. This task has been delayed following the introduction of SafeScript in 2019 due to urgent reprioritisation of DH resourcing as a result of the COVID-19 health pandemic.

Mid-term review
The medicines included in SafeScript will be part of the mid-term review of SafeScript as described in section 6.6 of the 2018 RIS. This review will occur once sufficient data to assess the operation of SafeScript is available. It is noted that the review of SafeScript has been delayed due to the impact of the COVID-19 health pandemic (including impacts on DH resourcing and priorities, and potential impacts of the pandemic on drug-related harms).

The mid-term review will assess whether:

- Inclusion of the medicines on SafeScript has achieved the intended objectives and benefits
- The costs and/or burdens placed on health professionals are higher or lower than anticipated
- There are any unintended costs, issues or other consequences that need to be addressed or managed.

Key Performance Indicators that will allow DH to better understand and report on whether the introduction of the proposed medicines into SafeScript has reduced harm include:

- Number of deaths where the proposed medicines have contributed compared to other prescription or illicit drugs (Coroners Prevention Unit)
- Number of patients supplied with the medicines (SafeScript data if available)
- Number of PBS prescriptions for other medicines that may be used to substitute for the proposed medicines (PBS data)

Further detail of how the mid-term review will be conducted is included in the 2018 RIS.

[178] Australian Commission on Safety and Quality of Health Care, *Opioid medicines dispensing, all ages, from 2016–17 to 2020–21*, available at https://www.safetyandquality.gov.au/our-work/healthcare-variation/opioid-medicines-dispensing-all-ages-2016-17-2020-21.

Appendix A Stakeholder consultation

Consultation informing this RIS

Stakeholder consultation was undertaken to gather relevant information on the options for the proposed regulations and their high-level impact. Consultation undertaken includes the following:

Austin Health report's consultation (December 2021)

- **Purpose of consultation:** Austin Health undertook a brief informal consultation process to gain a working understanding of the themes of potential impacts of inclusion of gabapentinoids and tramadol on SafeScript on both health care providers and patients. Consultation was undertaken to inform discussion within its report.
- **Format of consultation:** Relevant organisations were identified and invited to participate via email (see pg. 84 of report). A nominated representative from each organisation that responded then completed a semi-structured recorded interview using Microsoft Teams.
- **Who was consulted as part of review:** Several organisations were contacted and invited to participate in the informal scoping process and of the organisations contacted, six representatives were interviewed including: Australian Medical Association Victoria; Toxicology and Poisons Network Australasia; Victorian Addiction Inter-Hospital Liaison Association; Pharmaceutical Society of Australia Victoria; Pharmacy Guild of Australia Victoria Branch and the Victorian Poisons Information Centre.

Expert Advisory Committee on potential misuse of drugs of dependence[179]

- **Purpose of consultation:** To provide expert advice to the department on medical issues relating to drugs of dependence and their potential misuse
- **Format of consultation:** Meeting between the Department of Health and the Expert Advisory Committee in April 2022.
- **Members of committee:** include General Practitioners, pain specialists, addiction medicine specialists, community and hospital pharmacists, psychiatrist and consumer/patient advocacy groups.

[179] DH established an Expert Advisory Committee on potential misuse of drugs of dependence in 2018 consisting of clinical and content experts from the alcohol and other drug sector. The purpose of this group is to provide advice on the safe and effective management of all drugs of dependence for the Victorian community.

Appendix B PBS prescription data

Source: Appendix 2 2021 Austin Health review

Number of Prescriptions	PBS Stats	PBS Stats	PBS Stats
Victoria - total corrected FY	pregabalin	gabapentin	tramadol
2013/2014	377,770	24,447	625,552
2014/2015	631,763	25,800	658,713
2015/2016	790,382	25,999	644,384
2016/2017	894,840	26,579	618,177
2017/2018	938,535	29,051	598,983
2018/2019	937,307	30,924	582,772
2019/2020	902,739	32,997	541,177
2020/2021	922,891	36,446	414,602
Compound annual growth rate 2016/17 to 2019/20	**0.29%**	**7.48%**	**-4.34%**

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