

Statement of Reasons

Proposed Drugs, Poisons and Controlled Substances Amendment Regulations 2023

OFFICIAL

On the 23 February 2023, the Department of Health (the Department) released a Regulatory Impact Statement (RIS) to facilitate the consultation on the proposed Drugs, Poisons and Controlled Substances Amendment Regulations 2023 (the proposed Regulations). The public submission period closed on the 12 April 2023.

The Department received 18 submissions on the proposed Regulations and the RIS from:

Australian Medical Association - Victoria

Royal Australian College of General Practitioners – Victoria branch

Royal Australian and New Zealand College of Psychiatrists – Victoria branch

Rural Doctors Association of Victoria

Pharmaceutical Society of Australia – Victorian branch

The Pharmacy Guild of Australia – Victorian branch

Society of Hospital Pharmacists of Australia – Victorian branch

Chemist Warehouse Retail

Victorian Therapeutics Advisory Group

Coroners Court of Victoria

Pharmacy Board of Australia (Ahpra)

Dr Martyn Lloyd-Jones MBChB, MRCGP, FRACGP, FChAM

Dr David Jacka, Addiction Medicine Specialist

Dr Alexia Pape, Doctor of Medicine, University of Vienna

Monash Addiction Research Centre

Australian Rheumatology Association – Victorian and Tasmania

Avant

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) Clinical Pharmacology Specialist Interest Group (CPSIG)

16 submissions explicitly supported the proposed Regulations. Of these, some also included suggestions for implementation and raised issues outside the scope of the proposed Regulations.

Table 1 sets out a summary of the submissions, the response of the Department to the suggestions and issues raised in the submissions and a statement of reasons for each response.

After consideration of all the submissions, there is no changes to the proposed Regulations.

Drugs, Poisons and Controlled Substances Amendment Regulations 2023

Table 1. Summary of stakeholder submissions in response to RIS and exposure draft

Sub No.	Stakeholder	Submission summary	DH response
1	Australian Medical Association - Victoria	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript.</p> <p>AMA Victoria members frequently see the harms associated with misuse/overuse of these medications and are aware of the widespread use of these medications (particularly pregabalin and gabapentin) in people who use opioids. The overprescribing of these medications is also an issue of concern.</p>	No change
2	Royal Australian College of General Practitioners – Victoria branch	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript.</p> <ul style="list-style-type: none"> • ‘Many GPs have asked why these haven’t been previously included – as I interpret that, there’s an appetite for getting the ‘complete picture’ and not ‘escape’ medications. It will slightly increase the notifications, but the time involved is small and GPs should already have a smooth workflow around this, given it’s been nearly 3 years of mandatory use’ • ‘Gabapentin hasn’t been a huge misuse issue in Australia but in the UK, it is the preferred gabapentinoid to misuse 2:1 against pregabalin. It was not marketed well, and the prescribers didn’t start prescribing it as we did with Pregabalin. Safescript didn’t include it early based on economic analysis and a perceived increase in burden for GPs. I wanted the gabapentinoids included’ 	No change
3	Royal Australian and New Zealand College of Psychiatrists – Victoria branch	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript, with the following reasons:</p> <ul style="list-style-type: none"> - Abundant and increased evidence of harm associated with pregabalin - Victorian Coroner’s repeated recommendations to include pregabalin in SafeScript - Brings Victoria in line with other Australian jurisdictions like NSW and QLD with the medicines monitored by those states’ real-time prescription monitoring systems - International trends of harm associated with these medicines 	No change

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		<p>Recommends the following for the implementation of the proposed amendment:</p> <ul style="list-style-type: none"> - Update patient/consumer information on the addition of new medicines in SafeScript and what it means for them. - Education/training of target groups of practitioners including psychiatrists and psychiatrist trainees to <ul style="list-style-type: none"> • Emphasize that monitoring these medicines is consistent with recognising their associated harm and does not automatically trigger deprescribing. • Address withdrawal symptoms in tapering or cessation management plans. Consider access to additional medical advice and support e.g. DACAS, and addiction psychiatry. • Acknowledge that additional time may be required to check SafeScript in certain clinical contexts (e.g. prescription is infrequent). 	<p>The Department will update patient/consumer support material on the addition of pregabalin, gabapentin, and tramadol.</p> <p>The Department will update its online SafeScript training modules for clinicians to include information regarding pregabalin, gabapentin, and tramadol and provide relevant clinical resources for clinicians.</p>
4	Rural Doctors Association of Victoria	<p>Strongly supports the introduction of option 2 (inclusion of pregabalin, gabapentin, and tramadol monitored in SafeScript), with the following reasons:</p> <ul style="list-style-type: none"> - SafeScript is an invaluable resource for rural doctors as it allows them to enhance patient and consumer safety. - Option 2 will enhance consumer safety, minimise health care use burden, minimise high-risk prescription episodes of care, and minimise opportunities for unlawful use of medicines outside its prescribed intentions, ultimately leading to enhanced health for all Victorians. 	No change
5	Pharmaceutical Society of Australia – Victorian branch	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript as it will assist prescribers and dispensers to identify risks of harm at the time of providing advice and clinical services to an individual.</p> <p>Recommends the following:</p> <ul style="list-style-type: none"> - Listing the medicines in SafeScript based on drug class and schedule rather than specific medicines e.g. gabapentinoids as a class included, opioids as a class. This approach would ensure that regulatory change and consultative processes are only required when a new class of medicines that poses risks of harm is identified. 	<p>No change</p> <p>The Drugs, Poisons and Controlled Substances Regulations 2017 currently utilises schedules and classes of medicines rather than specific medicines where deemed appropriate. These include all Schedule 8 medicines and all</p>

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		<ul style="list-style-type: none"> - Consult with the Commonwealth and other jurisdictions to identify classes of medicines that will have an improved safety profile if included in SafeScript. If another jurisdiction monitors a medicine or class of medicines that is not included in SafeScript, Victoria should consider whether to include it as well. 	<p>benzodiazepines that are Schedule 4 medicines. For this amendment, the Department proposes to include pregabalin and gabapentin, rather than the class gabapentinoids to ensure direct alignment with other jurisdictions.</p> <p>The Department is currently working with the Commonwealth and jurisdictions on establishing cross-border data-sharing capabilities.</p>
6	The Pharmacy Guild of Australia – Victorian branch	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript to help reduce hospitalisation, avoid ED presentation, and save patient lives.</p> <p>Advocates for more resourcing and funding dedicated towards treatment and support services for patients identified with dependence or addiction. Supports proposals for a co-payment model where the Victorian Government funds dosing and clinical service fee for medication-assisted treatment of opioid dependence (MATOD).</p>	<p>No change</p> <p>Funding of MATOD is outside the scope of the proposed Regulations.</p>
7	Society of Hospital Pharmacists of Australia – Victorian branch	<p>Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript as it reduces patient harms arising from the use of medicines at risk of misuse and provides consistency with other states.</p> <p>Notes the importance of the pharmacist’s role in preventing associated harms and that risk of monitored medicine-related patient harm is not the sole responsibility of the prescriber.</p> <p>States that pharmacists should be involved in the delivery of take-home naloxone programs in hospitals and wherever medications are being used.</p>	<p>No change</p> <p>The take-home naloxone program is outside scope of the proposed Regulations. All hospital and community pharmacies are eligible to participate in the Commonwealth Government Take-Home Naloxone program.</p>

Sub No.	Stakeholder	Submission summary	DH response
8	Chemist Warehouse Retail	Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript as it promotes consistency across various jurisdictions.	No change
9	Victorian Therapeutics Advisory Group	<p>Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript, suggested the following considerations for implementation and monitoring:</p> <ul style="list-style-type: none"> - Non-mandatory check for these “lower risk” medicines - Whether storage and handling should be the same as other drugs of dependence in Victorian hospitals - Ongoing review of other medicines to include in SafeScript e.g. dihydrocodeine, pseudoephedrine - Additional regional services for regional patients e.g. addiction medicine, chronic pain services, rheumatology, neurology, and physiotherapy - Public messaging and consultation with the public around RTPM and the addition of proposed monitored medicines. 	<p>No change</p> <p>The Department considered non-mandatory use during the implementation of SafeScript. Data available showed that mandatory systems adopted in other countries demonstrated greater reduction in harms from high-risk prescription medicines.</p> <p>Standardising storage and handling of monitored medicines with drugs of dependence is outside the scope of proposed Regulations. The Department will consider this recommendation in future regulation amendments relating to storage and records.</p> <p>The Department continuously monitor harms caused by medicines and potential candidates to be included in SafeScript. Noting the progress towards implementation of the National Data Exchange to enable data sharing between jurisdictions it is anticipated that future changes to medicines monitored will be considered through a national process.</p> <p>Funding of additional regional services is outside scope of the proposed</p>

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			<p>Regulations. The Hamilton Centre Clinical Network was launched in April 2023 in response to Recommendation 36 of the Royal Commission into Victoria's Mental Health System. This service will provide addiction specialist support for people living with co-occurring mental illness and substance use or addiction. This initiative will increase addiction specialist access for regional Victoria.</p> <p>The Department invited public and consumer groups for this Regulatory amendment consultation. Patient material is available relating to real-time prescription monitoring. The roll-out of SafeScript was accompanied by two public awareness campaigns.</p>
10	Coroners Court of Victoria	Summarised ten coronial findings between 2017 and 2023 that include recommendations to include pregabalin in SafeScript.	No change
11	Pharmacy Board of Australia (Ahpra)	Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript as it supports alignment with other jurisdictions, which provides greater public protection and achieve harmonisation of systems that supports workforce mobility of health practitioners across Australia.	No change
12	Dr Martyn Lloyd-Jones MBChB, MRCGP, FRACGP, FChAM Specialist in Addiction Medicine	Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript - frequently sees the harms associated with misuse/overuse of these medications and widespread use of these medications (particularly pregabalin and gabapentin) in people who use opioids. The overprescribing of these medications is also an issue of concern.	No change

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	VMO Addiction and Mental Health		
13	Dr David Jacka Addiction Medicine Specialist Community Access and Partnerships Mental Health - Monash Health	<p>Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript for the following reasons:</p> <ul style="list-style-type: none"> - Tramadol is an opioid, although a weak one, and its dependence and abuse are not rare. Makes sense to include it in SafeScript to reinforce to prescribers, pharmacists, and consumers its addiction and abuse potential. Its absence in SafeScript impairs the full assessment of polysubstance abuse during acute illness. - The widespread abuse of gabapentin and pregabalin in sectors of the illicit methamphetamine-using community warrants greater scrutiny regarding their risk of abuse and dependence. - Inclusion in Safescript would assist in the prevention and appropriate treatment of withdrawal episodes. In addition, the dispensing information would also prevent inadvertent combination sedation overdose with the commencement of opioid pharmacotherapies. <p>The additional burden is easily balanced against the reduced risk of the combined toxicity of these three medications. It may also contribute to the reduced inappropriate prescribing and abuse of gabapentinoids.</p>	No change
14	Dr Alexia Pape Doctor of Medicine, University of Vienna	<p>Urges not to limit access to neuropathic pain killers too much with the following reasons:</p> <ul style="list-style-type: none"> - Some patients with diabetes require chronic pain relief and have limited resources to see health professionals due to out-of-pocket cost. If forced to see a doctor monthly to get scripts, patients will struggle with financial burden and quality of life. - Most doctors understand the risks of prescribing chronic painkillers and would only do so for patients where the benefits outweigh the risks. 	The Drugs, Poisons, and Controlled Substances Regulations 2017 allow a prescription for a Schedule 4 medicine to be issued for 12 months. The proposed amendment will not limit the duration of a prescription. SafeScript provides real time prescribing and dispensing information to assist clinical decision making. The system does not prevent a prescription being issued or limit the duration of a prescription issued.

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15	Monash Addiction Research Centre	Summarises their research which found evidence of a possible substitution effect where prescribing of pregabalin and tramadol appeared to increase relative to trends of declining prescribing prior to RTPM implementation.	No change
16	Australian Rheumatology Association – Victorian and Tasmania	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript with the following implementation recommendations:</p> <ul style="list-style-type: none"> - Enhance rheumatology services so that patients with musculoskeletal pain on gabapentinoids/tramadol are not left without viable alternatives or else patients may increase the risk of patients resorting to illicit opioids and increase mental health conditions such as suicidal tendencies due to poor pain management. - Consider the extra strain of this proposal on an already overburdened healthcare system. Victoria’s rheumatology services are inadequate and insufficient necessitating increased funding to address workforce shortages. 	<p>No change</p> <p>The recommendations for enhanced rheumatology services have been provided to the relevant program area in the Department of Health for further consideration. It is outside the scope of the proposed Regulations.</p>
17	Avant (medical indemnity insurer)	<p>Supports proposed amendment to monitor pregabalin, gabapentin, and tramadol in SafeScript as there are substantial risks of patient harm associated with these three medicines, reinforced in the Product Information.</p> <p>Notes that Avant’s Victorian members have indicated that SafeScript is a very valuable tool but felt “in the dark” about the complete patient medicine profile without pregabalin, gabapentin, and tramadol in SafeScript.</p> <p>Recommends the following:</p> <ul style="list-style-type: none"> - Information campaign to accompany the inclusion of pregabalin, gabapentin, and tramadol. - Facilitate all prescribers to check all patients across all jurisdictions when using SafeScript. Consideration should be given to an interim measure whilst jurisdictions work towards a national RTPM system. 	<p>No change</p> <p>The Department will be communicating to all prescribers, pharmacists, peak bodies and professional organisations in the lead up to the proposed Regulations commencing.</p> <p>Victoria is already part of the national RTPM platform and currently working with the Commonwealth and jurisdictions on establishing cross-border data-sharing capabilities.</p>

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18	The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) Clinical Pharmacology Specialist Interest Group (CPSIG)	Supports proposed amendment to monitor pregabalin, gabapentin and tramadol in SafeScript as misuse of gabapentinoids is well documented and there is data relating to tramadol harms, being one of the most commonly prescribed opioids in Australia.	No change