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Medicines and Poisons Regulation
Department of Health
GPO Box 4057
Melbourne VIC 3001

Avant Mutual Group Limited
ABN 58 123 154 898

Registered office
Level 6, Darling Park 3
201 Sussex Street, Sydney NSW 2000

Postal address
PO Box 746 Queen Victoria Building
Sydney NSW 1230

DX 11583 Sydney Downtown
avant.org.au

Telephone 02 9260 9000 **Fax** 02 9261 2921
Freecall 1800 128 268 **Freefax** 1800 228 268

By email: dpcs@health.vic.gov.au

DPCS Amendment Regulations 2023 response

Thank you for the opportunity to provide input into the public consultation on the inclusion of pregabalin, gabapentin and tramadol in SafeScript and the proposed Drugs, Poisons and Controlled Substances Amendment Regulations 2023.

Avant is a member-owned doctors' organisation and Australia's largest medical indemnity insurer, committed to supporting a sustainable health system that provides quality care to the Australian community. Avant provides professional indemnity insurance and legal advice and assistance to more than 82,000 healthcare practitioners and students around Australia (more than half of Australia's doctors). Our members are from all medical specialities and career stages and from every state and territory in Australia.

Our submission is attached.

Please contact me on the details below if you require any further information or clarification of the matters raised in this submission.

Yours sincerely



Georgie Haysom
General Manager, Advocacy, Research and Education
Direct: (02) 9260 9185
Email: georgie.haysom@avant.org.au

Avant submission to the public consultation on DPCS Amendment Regulations 2023

Avant is a mutual organisation, owned by its doctor members, and is Australia's largest medical indemnity insurer, providing professional indemnity insurance and legal advice and assistance to more than 82,000 healthcare practitioners and students around Australia. Over half of all Australian doctors are Avant members. Members come from all medical specialities and career stages, and every state and territory.

We assist members in civil litigation, professional conduct matters, coronial matters and a range of other matters. We have a Medico-legal Advisory Service that provides support and advice to members and insured medical practices when they encounter medico-legal issues. We also provide medico-legal education to our members with a view to improving patient care and reducing medico-legal risk. We have previously provided education material to Victorian members about the introduction and use of SafeScript.

General comments

Avant welcomes the Department of Health's consideration of options and the proposed Drugs, Poisons and Controlled Substances Amendment Regulations 2023 (**DPCS Amendment Regulations 2023**) for the inclusion of pregabalin, gabapentin and tramadol in the medicines monitored by Victoria's Real-time Prescription Monitoring (**RTPM**) system, SafeScript.

The options under consideration are:

- **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).

Avant supports Option 2.

Avant position – Support for Option 2

Avant supports the proposal to add pregabalin, gabapentin and tramadol to the medicines monitored in SafeScript (Option 2) as an important initiative for both patient care and safe medical practice in Victoria.

There are substantial risks of patient harm associated with all three medicines – pregabalin, gabapentin and tramadol, as the Regulatory Impact Statement (**RIS**) sets out.¹

These risks are reinforced in the Product Information for these medicines as follows.

The Product Information for Lyrica (pregabalin) states:

LYRICA is a potential drug of misuse, abuse, and dependence.

There have been post market reports of overdose and deaths among users of LYRICA, particularly with concomitant use of other sedating medicines, such as opioids and/or benzodiazepines.

¹ Carrick S, Hall M (2022) 'Regulatory Impact Statement – Schedule 5 & Schedule 6 of the Drugs, Poisons and Controlled Substances Regulations 2017', Victorian Department of Health, December 2022, pp15-29

The risk of misuse and abuse of LYRICA should particularly be monitored among current or past opioid and/or benzodiazepine users.

Patients should be carefully evaluated for a history of substance abuse prior to being prescribed LYRICA and observed for signs of LYRICA misuse or abuse (e.g., development of tolerance, increase in dose, drug seeking behaviour).

Very similar wording is in the Product Information for Neurontin (gabapentin).

Extracts from the Product Information for Tramal (tramadol) include:

Tramal® poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment.

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required.

Tramal® contains the opioid tramadol hydrochloride and is a potential drug of abuse, misuse and addiction.

The risk of addiction is increased in patients with a personal or family history of substance abuse (including alcohol and prescription and illicit drugs) or mental illness. The risk also increases the longer the drug is used and with higher doses. Patients should be assessed for their risks for opioid abuse or addiction prior to being prescribed Tramal®.

All patients receiving opioids should be routinely monitored for signs of misuse and abuse. Opioids are sought by people with addiction and may be subject to diversion. Strategies to reduce these risks include prescribing the drug in the smallest appropriate quantity.

Careful and regular assessment and monitoring is required to establish the clinical need for ongoing treatment. Discontinue opioid therapy if there is no improvement of pain and/or function during the trial period or if there is any evidence of misuse or abuse.

Tramadol is not recommended as a substitute in opioid-dependent patients.

Because of the difficulty in assessing dependence in patients who have previously received substantial amounts of opioid medications, caution should be used in the administration of tramadol to such patients.

In patients with a tendency for drug abuse or dependence, treatment with tramadol should only be carried out for short periods under strict medical supervision.

Avant is also aware of many coronial cases where misuse of one or a combination of the three medicines has been involved in an unexpected death.

Adding pregabalin, gabapentin and tramadol to SafeScript will provide an effective clinical tool to support safer prescribing and supply of these medicines and prevent misuse, including polypharmacy.

As the RIS details, patient harm from misuse of pregabalin and gabapentin remains high despite increased warnings from Victorian Coroners and the Therapeutic Goods Administration.² Avant's own experience is that some medical practitioners remain unaware of the drug dependency and diversion issues with pregabalin and gabapentin.

Tramadol has also been flagged as it is often overprescribed in complex chronic pain and has strong addiction potential.³ We also note that the frequency of overdose deaths where tramadol contributed increased steadily from 2011 until the COVID pandemic and remains considerably higher than a number of drugs already included in SafeScript.⁴

At the same time, SafeScript is widely used by medical practitioners and works well. Avant's members in Victoria have told us that SafeScript is a very valuable tool, but they feel left 'in the dark' about the complete patient medicine profile without pregabalin and gabapentin and tramadol in the database.

The inclusion of all three medicines in SafeScript will also provide an important step towards national consistency in real-time prescription monitoring for these three medicines.

All states and territories have now introduced RTPM programs, and most have already included all three medicines in their respective systems. By including pregabalin, gabapentin and tramadol in SafeScript, Victoria will align with the ACT, NT, Queensland, South Australia and Tasmania.

Avant position – Proposed DPCS Amendment Regulations 2023

Avant has no changes to the proposed DPCS Amendments Regulations 2023.

Further considerations

More broadly, Avant notes:

1. An information campaign is recommended to accompany the inclusion of pregabalin, gabapentin and tramadol in SafeScript.
 - Such a campaign should target medical practitioners and other prescribers so that they are made aware of the new requirements and can be prepared to adjust their workplace practices accordingly.
 - The campaign could also remind prescribers about the role of SafeScript in making more informed and safe clinical decisions when prescribing, to offset any reluctance to prescribe where they believe monitored medicines are clinically necessary.
2. Consideration should be given to enabling prescribers to check all patients across all jurisdictions when using SafeScript.
 - Avant has long supported national consistency for real-time prescription monitoring to support safer prescribing and prevent prescription medicines misuse.
 - Currently, not all RTPM systems allow prescribers to check for all patients across jurisdictions.

² Carrick S et al (2022), p19

³ *ibid*, p27

⁴ Coroners Court of Victoria (2021), Table 8, Victorian overdose deaths 2011-2020, 25 July 2021

- As states and territories continue to work towards the development of a national RTPM system, consideration should be given to an interim measure that enables all prescribers to check for all patients irrespective of where the practitioner and patient are located.
3. We continue to recommend that the process of checking SafeScript is not onerous for prescribers.

Avant Mutual

30 March 2023