ScriptCheckSA

Department for Health and Wellbeing

Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021

September 2021

Government of South Australia

SA Health

Introduction

- South Australia's Real-Time Prescription Monitoring (RTPM) system, **Script**Check**SA** was released state-wide on 31 March 2021.
- **Script**Check**SA** helps to address prescription forgery, misuse, and doctor-shopping relating to monitored drugs in South Australia (SA) by providing prescribers and pharmacists with real-time information about their patients' access to monitored drugs so that they can make safer clinical decisions about which medicines to prescribe or supply.
- Access to monitored drug prescription and dispensing data in real-time can help reduce misuse and harms associated whilst ensuring that patients who genuinely require monitored drugs can still access them.
- **Script**Check**SA** does not prevent health practitioners from prescribing or dispensing a monitored drug they consider to be clinically necessary for their patient. Health practitioners are still responsible for their own clinical decision making.
- Stakeholders have indicated that mandating the use of **Script**Check**SA** is essential to ensure its success and agree that this should occur; after a minimum period of 12 months following state-wide release and with appropriate training and support for health practitioners being made available.
- The time frame for mandating the use of **Script**Check**SA** is consistent with the period of voluntary use in Victoria before the use of SafeScript was mandated in April 2020.
- Free training, education and support resources have been developed for health practitioners and the community, and can be access via the **Script**Check**SA** landing page (www.scriptcheck.sa.gov.au) and **Script**Check**SA** website.
- Amendments to the Controlled Substances (Poisons) Regulations 2011 (CS Regs) are necessary to mandate the use of **Script**Check**SA**.
- The Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021 (Variation Regulations) (Attachment 1) detail the amendments required to mandate the use of **Script**Check**SA** and are in addition to the amendments made in November 2020, which enabled implementation of **Script**Check**SA**.
- Broadly, the amendments in the Variation Regulations:
    - Mandate the use of **Script**Check**SA** when a Schedule 8 drug is prescribed or dispensed, with exemptions from use to mirror those currently in place for Section 18A of the *Controlled Substances Act 1984* (Regulation 22 CS Regs),
    - Increase the monitored drug reporting frequency to fortnightly (from monthly), where it is not collected automatically in real-time, and
    - Mandate that all prescribers and pharmacists who use clinical software which has the capability to connect to a Prescription Exchange Service (PES), do connect so records are submitted to **Script**Check**SA** in real-time to help ensure that the monitored drug data is more complete.
    - Includes a data sharing provision under Regulation 53A to allow information in **Script**Check**SA** to be disclosed in accordance with an authorisation given by the Minster for Health and Wellbeing.
    - Minor administrative amendments and an amendment to Regulation 45A to align with a National Scheduling decision that is unrelated to RTPM.

- This consultation document further explains the proposed amendments relating to RTPM and their implications for SA prescribers and pharmacists. This document is presented alongside the Variation Regulations to seek feedback from stakeholders and the public on the proposed amendments (Attachment 1).
- **Please note** that the amendments in the Variation Regulations do not propose any changes to the exemptions currently in place for Section 18A of the *Controlled Substances Act 1984* (Regulation 22 CS Regs) and as a result, this consultation will not be seeking feedback on these exemptions.
- Consultation with industry on the amendments to Regulation 45A has already taken place through the standard scheduling decision consultation framework and therefore, feedback on these amendments is not being sought as part of this public consultation.
- For further information or clarification on the amendments in the Variation Regulations, please contact the **Script**Check**SA** Project Team via phone (08 8226 7100) or email (Health.RTPM@sa.gov.au).

Controlled substances (Posions) RTPM Variation Regulations 2021

Definitions

When reviewing the Variation Regulations, please note the following definitions as stated in Regulation 3 of the CS Regs:

- ***Data source entity*** *means any of the following:*
  (a) eRx Script Exchange Pty Ltd;
  (b) MediSecure Pty Ltd;
  (c) Medication Knowledge Pty Ltd;
  (d) a prescription exchange service operating in an Australian jurisdiction;

The term '*Data source entity'* has been defined in the CS Regs to legally distinguish which clinical software is connected to a PES (i.e. eRx or MediSecure). This distinction is required as only clinical software that is connected to a PES will automatically transmit monitored drug data to **Script**Check**SA**. Prescribers and pharmacists who are NOT connected to a PES, unless otherwise exempt, must submit monitored drug data manually (via a report) to the Department for Health and Wellbeing Chief Executive (i.e. Drugs of Dependence Unit (DDU)).

- ***monitored drugs database*** *means an electronic database kept by the Department that contains information relating to the sale, supply, prescription, administration and use of monitored drugs;*

The term '*monitored drugs database'* refers to SA's RTPM system, **Script**Check**SA**.

- ***monitored drug*** *means any of the following:*
  (a) any S8 poison;
  (b) any S4 poison that is a benzodiazepine;
  (c) any S4 poison that contains Codeine;
  (d) any of the following S4 poisons:
  (i) Gabapentin;
  (ii) Pregabalin;
  (iii) Quetiapine;
  (iv) Tramadol;
  (v) Zolpidem;
  (vi) Zopiclone;

The prescription drugs monitored in **Script**Check**SA** are those that cause the greatest harm to the South Australian community. The Schedule 4 (S4) drugs have been included because they increase the potential harms associated with Schedule 8 (S8) drugs (drugs of dependence) if co-prescribed. The list of monitored drugs will be periodically reviewed and new S4 drugs added or removed over time if they meet the inclusion criteria. Any new S8 drugs will always be monitored in **Script**Check**SA**.

Connection to a Prescription Exchange Service (PES)

Monitored drug prescription and dispensing data from clinical software that is not connected to a PES is not available in **Script**Check**SA**. Monitored drug data from non-PES connected software is submitted manually to the DDU each month (in arrears) and is available to health practitioners by contacting DDU. However, this data is not real-time and can be up to six weeks old.

Therefore, to ensure that the data available for health practitioners to access in **Script**Check**SA** is more complete, prescribers and pharmacists who use clinical software which has the capability, will be required to register and connect to a PES (i.e. eRx or MediSecure).

- Regulation 33(6)(b) will be amended to:

  *If a prescription for a monitored drug for human use is prepared in an approved electronic form, the **prescriber** must - transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (6a) applies).*

- Regulation 34(1a)(b) will be amended to:

  *A **prescriber** who writes a prescription for the supply of a monitored drug for human use - if the record is kept in electronic form—must transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (1b) applies).*

- Regulation 35A(1)(b) will be amended to:

  *A **pharmacist** who dispenses a monitored drug on prescription must – transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (2) applies).*

An Expiation Fee has been added to Regulation 35A(1) to be consistent with the Expiation Fee for prescribers in Regulations 33(6) and 34(1a).

Regulations 33(6)(b) and 34(1a)(b) will not change the existing requirements for handwritten monitored drug prescriptions.

Prescribers and pharmacists should contact their software provider to confirm if their clinical software can connect to a PES and if so, how to register with a PES provider (i.e. eRx or MediSecure) and enable the PES connection. The majority (95%) of SA pharmacies are already connected to a PES and therefore will not be affected by Regulation 35A(1)(b).

The ScriptCheckSA Project Team, as part of this consultation, would value input from stakeholders as to whether there are any groups of prescribers (who use clinical software) or pharmacists who should be considered for exemption from Regulations 33(6)(b), 34(1a)(b) or 35A(1)(b), and why providing an exemption would be appropriate.

Monitored drug reporting frequency

Not all clinical software has the capability to connect to a PES and prescribers and pharmacists using this type of clinical software must manually submit a Monitored Drugs Report monthly (by the 7th day of each month for the previous month's data) to the DDU. This data is available to health practitioners by contacting DDU but can be up to six weeks old.

To ensure that the manually submitted data is more current and relevant to health practitioners as part of their clinical decision making), the manual reporting frequency will be increased from monthly to fortnightly.

- Regulations 33(6a) will be amended to:

> *If a **prescriber** is unable to transmit a record relating to a prescription in accordance with subregulation (6)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the **prescriber** must transmit the record electronically to the Chief Executive so that it is received no later than—*
>
> *(a) if the prescription is prepared on a day falling within the first 14 days of a month—the 21st day of that month; or*
>
> *(b) if the prescription is prepared on any other day—the 7th day of the month following the month in which the prescription was prepared; or*
>
> *(c) in any case, such later day as the Chief Executive may, on application, authorise.*
>
> *Maximum penalty: $5 000.*
>
> *Expiation fee: $1 250.*

- Regulation 34(1b) will be amended to:

> *If a **prescriber** is unable to transmit a record relating to a prescription in accordance with subregulation (1a)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the **prescriber** must transmit the record electronically to the Chief Executive so that it is received no later than—*
>
> *(a) if the prescription is written on a day falling within the first 14 days of a month—the 21st day of that month; or*
>
> *(b) if the prescription is written on any other day—the 7th day of the month following the month in which the prescription was prepared; or*
>
> *(c) in any case, such later day as the Chief Executive may, on application, authorise.*
>
> *Maximum penalty: $ 5 000.*
>
> *Expiation fee: $1 250.*

- Regulations 35A(1a) and (2) will be amended to:

> *If a **pharmacist** is unable to transmit a record relating to a prescription in accordance with subregulation (1)(b) because the electronic system used to make the record is not compatible with the electronic system of a data source entity, the **pharmacist** must transmit the record electronically to the Chief Executive so that it is received no later than—*
>
> *(a) if the drug is dispensed on a day falling within the first 14 days of a month—the 21st day of that month; or*
>
> *(b) if the drug is dispensed on any other day—the 7th day of the month following the month in which the drug was dispensed; or*
>
> *(c) in any case, such later day as the Chief Executive may, on application, authorise.*
>
> *Maximum penalty: $ 5 000.*
>
> *Expiation fee: $1 250.*

Regulations 33(6a), 34(1b) and 35A(2) allows prescribers and pharmacists ONE week (after the fortnight ends) to extract monitored drug data from their clinical software and submit the report to the DDU. Therefore, a monitored drug prescribed or dispensed in the first 14 days of the month must be

reported by the 21st day of that month. A monitored drug prescribed or dispensed in the last 14 days of the month must be reported by the 7th day of the following month.

This increased reporting frequency will only affect the small percentage (5%) of pharmacies using clinical software that does not have the capability to connect to a PES.

It is acknowledged that this requirement may place an additional burden on a significant number of prescribers using clinical software that does not have the capability to connect to a PES.

A Ministerial exemption exists for Regulations 34(1a)(b) and 34(1b) to enable the Minister for Health and Wellbeing to exempt certain groups of prescribers from the reporting requirement.

- For consistency, an exemption will be added to Regulations 33(6a) and 33(6)(b):

> *The Minister may exempt a **prescriber** or class of **prescribers** from the operation of subregulation (6)(b) or (6a) (or both) if satisfied that proper cause exists for the exemption.*

In cases where an exemption is granted, the monitored drug prescription data would still be captured in **Script**Check**SA** at the point of dispensing if the pharmacy is connected to a PES.

The below reporting requirement in Regulation 35A(2) will be deleted:

> *A **pharmacist** in charge of a pharmacy at which no drugs of dependence are dispensed for a period of 30 consecutive days must, no later than the 7th day of the month following the month during which the 30th day of that period falls, notify the Chief Executive of that fact in writing.*
> *Maximum penalty: $5 000.*

The ScriptCheckSA Project Team, as part of this consultation, would value input from stakeholders as to the groups of prescribers who should be considered for exemption from this reporting requirement and the reasons why this would be appropriate.

Mandatory use of ScriptCheckSA

Experience from the United States suggests that real-time prescription monitoring systems (referred to as Prescription Drug Monitoring Programs (PDMPs)) must be fully utilised in order to reach their full potential in minimising harms and diversion associated with high-risk prescription medicines.[1] The states of Tennessee and New York found that mandating the use of PDMPs rapidly increased enrolment and use of PDMPs and that as the rate of use increased, measures of 'doctor shopping' and prescribing of high-risk prescription medicines declined.[1]

Stakeholders have indicated that mandating the use of **Script**Check**SA** should occur after at least 12 months of voluntary use (i.e. 1 April 2022). This is consistent with Victoria where the use of SafeScript was mandated in April 2020 to allow users time to become familiar with the system.

Prior to prescribing or dispensing an S8 drug, AHPRA registered prescribers and pharmacists will be required to take all reasonable steps to check the information available in **Script**Check**SA**. The information in **Script**Check**SA** could be accessed by:

[1] PDMP Center of Excellence at Brandeis University. *Mandating PDMP participation by medical providers: current status and experience in selected states*. 2014. Available at: https://www.ojp.gov/pdffiles1/bja/247134.pdf

- Clicking though a red or amber pop-up notification that appears on a prescriber or pharmacists' desktop (for those using clinical software that is connected to a PES)
- The secure **Script**Check**SA** web portal (available at: www.scriptcheck.sa.gov.au)
- Contacting the DDU to request information about their patient's monitored drug history.

A green pop-up notification indicates that no alerts have been triggered for the patient and will be considered to meet the obligation to be aware of the information in **Script**Check**SA** and therefore no additional access will be required.

- A new Regulation 34A(1)

> *Before a **prescriber** gives a prescription for the supply of a drug of dependence for human use (whether the prescription is given in writing, in an approved electronic form, by telephone, by fax or by an approved electronic communication), the **prescriber** must take all reasonable steps to access the information held in the monitored drugs database relating to the person for whom the drug is to be prescribed.*
> *Maximum penalty: $5 000.*

- And a new Subregulation 35A(4)(aa) will be added:

> *A **pharmacist** or medical practitioner must not - dispense a drug of dependence unless the pharmacist or practitioner has taken all reasonable steps to access the information held in the monitored drugs database relating to the person for whom the drug is to be dispensed; or*

This requirement is in addition to the existing requirements in Subregulation 35A(4)(a) and (b).

A maximum penalty of $5 000 has been added for failure to comply with Regulations 34A(1) and 35A(4)(aa). The Regulator (DDU) will monitor for non-compliance by reviewing **Script**Check**SA** access logs, to verify if a patient's record has been accessed by the prescriber or pharmacist who has prescribed or dispensed the S8 drug.

Stakeholders should note that mandatory use of **Script**Check**SA** applies only when prescribing or dispensing an S8 drug. However, this does prevent prescribers or pharmacists from accessing the information in **Script**Check**SA** when prescribing or dispensing an S4 monitored drug should they wish to consider this information as part of their clinical decision making.

The mandatory use requirements in Regulations 34A(1) and 35A(4)(aa) should not be confused with the requirement to submit monitored drug data to **Script**Check**SA** or DDU, which applies to all monitored drugs, not just S8 drugs (Regulations 33(6)&(6a), 34(1a)&(1b), 35A(1)&(2)).

The ScriptCheckSA Project Team, as part of this consultation, would value input from stakeholders on whether it should be made mandatory that prescribers and pharmacists check the information available in ScriptCheckSA when prescribing or dispensing any monitored drug, not only an S8 drug and if so, for what reasons.

As part of this consultation, the ScriptCheckSA Project Team would also value input from stakeholders as to whether 12 months voluntary use is an appropriate time frame for mandating the use of ScriptCheckSA and if not, for what reasons.

Exemptions from mandatory use of ScriptCheckSA

It is acknowledged that there are some situations where it may not be practicable or appropriate for prescribers and pharmacists to access the information in **Script**Check**SA** prior to prescribing or dispensing an S8 drug to a patient. Therefore, stakeholders agree that exemptions from mandatory use should exist and that it would be appropriate for these exemptions to mirror those currently in place for Section 18A *Controlled Substances Act 1984* (regulation 22 CS Regs).

Stakeholders suggested that mirroring the current Section 18A exemptions would ensure consistency across the Controlled Substances legislation and avoid confusion with the requirements for prescribing S8 drugs. This would also allow time for sufficient data to be available to determine the groups of patients most at risk of harm from monitored drugs, which would help inform future review of the exemptions.

- A new Regulation 34A(2) will be added to exempt **prescribers** from being required to access the information in **Script**Check**SA** when prescribing an S8 drug in certain situations:

Subregulation (1) does not apply if—

(a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

(b) the drug (not being dextromoramide or pethidine) is for use by a person whose life expectancy is reasonably believed by the registered health practitioner principally responsible for treatment of the person, to be less than 12 months and—

(i) the prescriber has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed; and

(ii) the prescription for the drug is endorsed either "Notified Palliative Care Patient" or "NPCP"; or

c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution (within the meaning of the Correctional Services Act 1982) and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.

A new Subregulation 35A(6) will be added to exempt **pharmacists** from being required to access the information in **Script**Check**SA** when dispensing an S8 drug in certain situations:

Subregulation (4)(aa) does not apply if—

(a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or
(b) the prescription for the drug (not being dextromoramide or pethidine) is endorsed either "Notified Palliative Care Patient" or "NPCP"; or
(c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) *the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.*

It should be noted that even where an exemption applies, a prescriber or pharmacist can choose to access their patient's record in **Script**Check**SA** to inform their clinical decision making.

The ScriptCheckSA Project Team, as part of this consultation, would value input from stakeholders on whether the exemptions from mandatory use are appropriate and/or whether there are any additional exemptions that should be considered and if so, why.

Additional data sharing provision

Parliamentary Counsel has advised that an additional data sharing provision under Regulation 53A should be added to allow information in **Script**Check**SA** to be disclosed in accordance with an authorisation given by the Minster for Health and Wellbeing under circumstances where there is merit in disclosure (Section 60A(1)(e) of the *Controlled Substances Act 1984*).

A new Subregulation 53A(4) will be added:

Information contained in the monitored drugs database may be disclosed in accordance with an authorisation given by the Minister.

This Subregulation would allow the Minister a power to authorise the disclosure of information contained in **Script**Check**SA** if a circumstance arose where the Minister considered it appropriate to do so. For example, disclosure of information in **Script**Check**SA** to the South Australian Coroner, or the wife/husband/de factor/partner/parent of a deceased person.

It is common for this type of provision to be included in legislation, for example Section 93 of the *Health Care Act 2008*, provides the Chief Executive of the Department for Health and Wellbeing and CEOs of the Local Health Networks (LHNs) power to authorise the disclosure of personal information obtained under the Act.

Minor administrative amendments

For consistency, the definition for '*correctional institution'* will be deleted from Regulation 22(3) and added to Regulation 3(1) as this section details the definitions for terms mentioned in the CS Regs:

- ***correctional institution*** has the same meaning as in the *Correctional Services Act 1982*;

Commencement date

The Variation Regulations will commence on 1 April 2022.

Adoption of the Variation Regulations will ensure that all AHPRA registered prescribers and pharmacists make themselves aware of the information in **Script**Check**SA** (unless an exemption applies) prior to prescribing or dispensing a S8 drug to a patient. Being aware of a patient's monitored drug history prior to prescribing or dispensing a S8 drug will ensure that prescribers and pharmacists have the most current and up-to-date information to inform their clinical decision making regarding the care of their patient.

Feedback

The **Script**Check**SA** Project Team, Drugs of Dependence Unit (DDU) is seeking feedback on the Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021.

Support for, comments, or proposed amendments should be presented with supporting evidence where appropriate.

Written submissions, including your name, position and organisation (if appropriate) should be emailed to Health.RTPM@sa.gov.au or sent to CS Regs: **Script**Check**SA** Project, Drugs of Dependence Unit (DDU), PO Box 6, Rundle Mall, Adelaide, SA 5000.

Comments are requested by 12pm midday on Monday 1 November 2021

If you wish your details/specific details of your submssion or supporting evidence supplied to remain confidential, please note this clearly in your submission.

Further information or clarification on the amendments in the Variation Regulations can be obtained by contacting the **Script**Check**SA** Project Team via phone (08 8226 7100) or email (Health.RTPM@sa.gov.au).

Next Steps

Following this 5 week consultation period, the Settled Regulations, with or without changes depending on the submissons received, will be considered for approval. Where significant changes are proposed then a subsequent consulation period may be conducted.

Following approval, the Settled Regulations will be made by the Governor in Executive Council and published in the Government Gazette. Once made, the regulations are laid before both Houses of Parliament within six sitting days and are considered by the *Legislative Review Committee.* The regulations will come into operation on the date defined in the Settled Regulations (1 April 2022).

Details relating these amendments will be communicated to stakeholders (including prescribers and pharmacists) via the **Script**Check**SA** Website and through the following key stakeholder partners:

Membership of the **Script**Check**SA** Governance Board (SGB) includes:

- Deputy Chief Public Health Officer (CPHO), SA Health - Chair
- Drug and Alcohol Services SA (DASSA), SA Health
- Office of the Chief Pharmacist, SA Health
- Commission on Excellence and Innovation in Health (CEIH), SA Health
- Digital Health SA, SA Health
- Drugs of Dependence Unit (DDU), SA Health

Membership of the **Script**Check**SA** External Advisory Group (EAG) includes:

- CPHO - Chair
- Aboriginal Health Council of SA (AHCSA) – corresponding member
- Adelaide Primary Health Network (PHN)
- Australian College of Nurse Practitioners (ACNP)
- Australian Dental Association (ADA)
- Australian Medical Association (AMA)
- Chapter of Addiction Medicine (AChAM), Royal Australasian College of Physicians (RACP)
- Consumer representation
- DASSA
- Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (ANZCA)
- Medical Software Industry Association (MSIA)

- Office of the Chief Pharmacist
- Pharmaceutical Society of Australia (PSA)
- Pharmacy Guild of Australia
- Royal Australian and New Zealand College of Psychiatrists (RANZCP)
- Royal Australian College of General Practitioners (RACGP)
- SA Pharmacy
- SA Police (SAPOL)
- Society of Hospital Pharmacists of Australia (SHPA)
- South Australian Network of Drug and Alcohol Services (SANDAS)

Attachment 1 – Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021.

Appendix

Notifications

If a prescriber or pharmacist is using clinical software that is connected to a PES, red, amber or green messages will pop-up on their desktop when they are prescribing or dispensing a monitored drug to a patient. Notifications contain a click through link to the patient's record in **Script**Check**SA**. These notifications are designed to quickly and clearly signal to the prescriber or pharmacist if checking the patient's record in **Script**Check**SA** is required. To maintain patients' privacy, there is no clinical information contained in the notifications and prescribers and pharmacists are required to log into **Script**Check**SA** to view their patient's record and details of any alert(s) triggered.

Alerts

Exist within a patient's record in **Script**Check**SA** and indicate that the prescription or dispensing history for the patient has met SA-specific criteria for medium (amber alert) or high-risk (red alert) circumstances. Prescribers and pharmacists should consider information relating to an alert as part of their clinical decision-making prior to proceeding with prescribing or dispensing the monitored drug. However, they do not prevent a prescriber or pharmacist from prescribing or dispensing a monitored drug they consider to be clinically necessary for their patient. Health practitioners are still responsible for their own clinical decision making. Prescribers and pharmacists can only access **Script**Check**SA** and view alerts for their patients if they have registered for **Script**Check**SA** via: www.scriptcheck.sa.gov.au.

For more information

ScriptCheckSA
Drugs of Dependence Unit
Po Box 6, Rundle Mall
Adelaide, South Australia 5000
Telephone: 1300 652 584
Email: Health.RTPM@sa.gov.au
www.sahealth.sa.gov.au/scriptchecksa

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