

Schedule 8 treatment permits

Requirements in Victoria

(COVID-19 variation)

Public health emergency order (PHEO)

A public health emergency order, pursuant to section 22D of the Drugs Poisons and Controlled Substances Act 1981, was issued to remove requirements for registered medical practitioners and nurse practitioners to obtain a Schedule 8 treatment permit for patients who are **not drug-dependent persons – provided the practitioner checks the patient's SafeScript profile before prescribing**.

The PHEO will remain in effect, for the duration of the order or until revoked. The PHEO may be examined at <https://www2.health.vic.gov.au/public-health/drugs-and-poisons>

Drug-dependent persons

Other than where a general exception applies, a medical practitioner or nurse practitioner **must obtain a permit before treating a drug-dependent person with a Schedule 8 medicine**.

Medicines and Poisons Regulation will not be processing or issuing Schedule 8 permit applications for patients who are not drug-dependent during this period.

General exceptions (prisons, gaols, residential aged care services, inpatients)

In circumstances where patients are confined or not personally managing their medicines, the risk of concurrent prescribing and prescription-shopping is significantly reduced. Accordingly, a permit is not required to prescribe Schedule 8 medicines for:

- prisoners being treated in a prison or police gaol
- patients receiving inpatient treatment in a hospital
- patients receiving treatment in a hospital emergency department or a day procedure centre
 - **Note:** Each of the above exceptions **includes** a period not exceeding 7 days following the release or discharge of the person from the corresponding establishments.
- Residents being treated in a residential aged care service

What is a drug-dependent person?

The term 'drug-dependent person' is **not** applicable only to illicit drug users; it also relates to persons with iatrogenic dependence, for whom illicit drug use is not a consideration.

While the [Diagnostic and Statistical Manual of Mental Disorders Fifth Edition \(DSM-V\)](https://www.psychiatry.org/psychiatrists/practice/dsm) <<https://www.psychiatry.org/psychiatrists/practice/dsm>> and the [International Classification of Diseases 10th Revision \(ICD-10\)](https://www.who.int/classifications/icd/icdonlineversions/en/) <<https://www.who.int/classifications/icd/icdonlineversions/en/>> may provide assistance for clinicians to diagnose the condition, the Drugs Poisons and Controlled Substances Act 1981 does not define the term 'drug-dependent person'. It refers instead to when a practitioner has **reason to believe** a patient is a drug-dependent person.

The following list contains some examples of circumstances that might (or should) represent a reason to believe a patient is a drug-dependent person, especially when multiple circumstances apply:

- Admitted current misuse or abuse of pharmaceutical drugs and/or illicit drugs
- Prescription-shopping and/or obtaining prescription drugs from illicit sources
- Physical signs of intravenous drug use
- Forging prescriptions or obtaining drugs of dependence by false representation
- Multiple unsanctioned dose escalations of prescribed drugs
- Current or recent treatment with opioid-replacement therapy for opioid-dependence

SafeScript

SafeScript is Victoria's real-time prescription monitoring database; it allows medical practitioners, nurse practitioners and pharmacists to readily view recent records of monitored medicines dispensed for patients so that they may make better informed, safer decisions around whether to prescribe or supply a monitored medicine.

Since 1 April 2020, medical practitioners and nurse practitioners are required to check the SafeScript database before prescribing a monitored medicine to a patient (unless a specific exception applies). This requirement has been included as a condition, in the public health emergency order, which removes many of the Schedule 8 permit requirements during the duration of that order. All Schedule 8 medicines are monitored medicines.

For full details and exceptions relating to SafeScript, please refer to pages 3, 4 and 5.

More information about [SafeScript](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript) <<https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript>> (including online educational and training options), can be found on the Health.vic website.

To register to use SafeScript, go to the [SafeScript website](https://www.safescript.vic.gov.au/) <<https://www.safescript.vic.gov.au/>> .

Essential information about taking 'all reasonable steps'

The requirement for a practitioner to take '**all reasonable steps**' occurs in many regulations; it is not a new requirement.

- It is a subjective phrase that is intended to provide flexibility of approach according to the circumstances.
- It is important that practitioners have an understanding of how to achieve compliance with this requirement.
 - Please refer to the following text for a detailed explanation and examples of how compliance might be achieved or assessed.

Where the regulations require practitioners to take 'all reasonable steps' (e.g. regulations 17(c) and 17(e) for medical practitioners); an objective test must be applied to the particular circumstances as to whether or not the steps taken were sufficient. Such a test would involve considering if the steps taken would be in accordance with those a member of the profession, would take if put in that situation.

Quantity and repeats

Whereas a practitioner might be considered to have taken all reasonable steps to justify prescribing a minimal quantity of a Schedule 8 medicine; the same steps might not be considered to be sufficient to justify prescribing (or supplying) a larger quantity of the drug and/or to authorise repeat supplies.

Identity of a patient

Practitioners are required to take 'all reasonable steps' to ascertain the identity of a person when a **drug of dependence** is to be prescribed, supplied or administered by them. If that person is not already known to the practitioner, all reasonable steps might include examining photo identification, such as a Driver's Licence, and confirming the patient's date-of-birth.

Note:

- If a prescription is issued for a Schedule 8 medicine (or another monitored supply medicine), the prescriber must also include the patient's date of birth on the prescription.
- If a practitioner issues a prescription with the incorrect date-of-birth or an incorrectly spelt patient's name; details of the prescription might not be accurately recorded on the SafeScript database.
- Some prescription-shoppers deliberately provide false names or inaccurate details in an attempt to deceive; so it is important for prescribers to seek photo identification (e.g. Driver's Licence) and confirm the date-of-birth of any new or unfamiliar patients.

Therapeutic need

Practitioners are generally required to take 'all reasonable steps' to ensure that a therapeutic need exists before they prescribe or otherwise authorise treatment with any Schedule 3, Schedule 4 or Schedule 8 medicine. To satisfy this requirement, some or all of the following factors should be taken into account:

With respect to the person who requests the substance or the person (or animal) for whom it is proposed to prescribe or supply the substance -

- the medical history of the patient
- the prescribing history of the patient
- the presenting symptoms or described condition
- any signs or knowledge of misuse or abuse of medicines or illicit drugs

With respect to the substance requested, or that is to be prescribed (or supplied) –

- its suitability for the treatment of the presenting symptoms or described condition
- its **potential for misuse or abuse**
- the **quantity to be prescribed** (or supplied) – as indicated above

When a person is well known to the practitioner and the therapeutic need has been previously established, very little effort might be required in taking 'all reasonable steps' to ensure a therapeutic need exists.

However, for a new patient, a more thorough effort is likely to be required to satisfy this requirement, especially where there is reason to suspect abuse or misuse of medicines or illicit drugs.

In these and other circumstances, 'all reasonable steps' **might** include:

- examining the patient
- arranging for diagnostic tests (where applicable) to justify initial or ongoing treatment
- confirming the patient's claims by contacting previous prescribers
- confirming the authenticity of reference letters or diagnostic tests provided by the patient
- checking Victoria's SafeScript database

Using SafeScript

Monitored supply medicines

- all Schedule 8 medicines
- all benzodiazepines (e.g. diazepam; clonazepam)
- 'Z-drugs' (zolpidem, zopiclone)
- quetiapine
- codeine containing products

Mandatory checking of the SafeScript database (from 1 April 2020)

The Drugs, Poisons and Controlled Substances Act 1981 (s.30E, s.30F, s.30G) makes provision for penalties to be imposed when medical practitioners, nurse practitioners or pharmacists fail to take 'all reasonable steps' to check the SafeScript database before prescribing or supplying a monitored supply medicine – unless otherwise specified in regulations 132F, 132G or 132H; (e.g. hospitals, prisons, police gaols, aged care and palliative care).

- While SafeScript has been designed to integrate with clinical workflows for clinicians using prescribing software, prescribers do not need to use their medical practice software to access the SafeScript database.
- Prescribers can access SafeScript directly (<https://www.safescript.vic.gov.au/>) via their internet browser.
- Prescribers who issue paper prescriptions can also access the SafeScript portal using mobile or tablet devices.

The phrase 'all reasonable steps' takes into consideration the possibility that, in addition to specified exceptions, there may be circumstances where practitioners may not be able to check the SafeScript database before prescribing or supplying a monitored supply medicine. Accordingly, before considering whether action might be required in relation to non-compliance, the department will take account of the steps that were taken by a practitioner to attempt to satisfy this requirement plus any mitigating circumstances. For example, if access to the SafeScript database is temporarily unavailable:

- Contacting a pharmacy to enquire about a patient history in SafeScript
- Prescribing or supplying **limited quantities** and checking SafeScript at the next available opportunity

However, practitioners who do not check the SafeScript database simply because they have not registered to do so or have not arranged access to a computer (or other device), and do not take other measures to review a patient's history in SafeScript, are unlikely to satisfy this requirement.

If practitioners are unable to check the SafeScript database, they would be expected to:

- make a prominent contemporaneous record of the fact and the reason they were unable to do so; to ensure that they (or colleagues) are aware, when the patient next attends, that the check was not done
- take all reasonable steps to ensure that they will be able to do so at the earliest opportunity; for example:
 - If the practitioner has not registered to use SafeScript; to do so without delay.
 - If a clinic does not have a suitable internet connection:
 - ensure that another device (e.g. tablet or phone) can be used to connect to SafeScript
 - inform the proprietor/employer (in writing) of the need to arrange a suitable internet connection and forward a copy of that written advice to MPR.

Specified exceptions to mandatory checking of SafeScript

The following categories (in regulations 132F, 132G and 132H) will be exceptions:

A pharmacist will not be required to check SafeScript before supplying a monitored supply person to:

- an in-patient being treated in hospital (**not** including discharge medicines);
- a patient being treated in an emergency department of a hospital (**not** including discharge medicines);
- a prisoner being treated in a prison;
- a person being treated in a police gaol;
- a resident being treated in an aged care service.

Medical practitioners and **nurse practitioners** will not be required to check SafeScript before prescribing or supplying a monitored supply person to:

- an in-patient being treated in, or discharged from, a hospital;
- a patient being treated in, or discharged from, an emergency department of a hospital;
- an out-patient being treated in, or discharged from, a hospital;

- **Note:** Whilst medical practitioners and nurse practitioners, working in hospitals (as per the three preceding dot points) are not legally required to check SafeScript; they are encouraged to do so to ensure that they are aware of information that might impact on the health and well-being of their patients.
- a prisoner being treated in a prison;
- a person being treated in a police gaol;
- a resident being treated in an aged care service.

Incurable medical condition

Medical practitioners, nurse practitioners and pharmacists will not be required to check SafeScript before prescribing or supplying a monitored supply medicine to a person if:

- the person is suffering an incurable, progressive, far-advanced disease or medical condition; **and**
- the prognosis is of a limited life expectancy due to the disease or medical condition; **and**
- the supply of the monitored supply medicine is intended to provide palliative treatment.

For further information

Department of Health & Human Services (DHHS)

Medicines and Poisons Regulation

GPO Box 4057
Melbourne 3001

Tel: 1300 364 545

Fax: 1300 360 830

Email: dpcs@dhhs.vic.gov.au

Web: www2.health.vic.gov.au/dpcs

Documents to print or download from the MPR website

The [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <<http://www.health.vic.gov.au/dpcs>> on the Health.vic website in the section for Documents to print or download, contains summaries of legislative requirements that have been prepared in relation to issues that relate to multiple categories of health practitioner as well as to individual categories of health practitioner. These documents, which are intended to assist health practitioners to comply with key legislative requirements, include the following:

- **Issues relating to multiple categories of health practitioner, including:**
 - Possession and storage
 - Supply, administration and records
 - Prescribing
 - Criteria for lawful prescriptions
 - All reasonable steps and other key terms
 - Schedule 2 and 3 poisons

To receive this publication in an accessible format phone 1300 364 545, using the National Relay Service 13 36 77 if required, or [email dpcs@dhhs.vic.gov.au](mailto:dpcs@dhhs.vic.gov.au)

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

© State of Victoria, Department of Health and Human Services April, 2020.