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| ‘All reasonable steps’ (and other key terms) |
| Information for health practitioners |
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# Introductory notes

The *Drugs Poisons and Controlled Substances Act 1981* (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the regulations) indicate who may possess Schedule 4 and 8 poisons; the extent to which possession is lawful; and the legislative requirements for use, storage and supply of Schedule 4 and 8 poisons. Current versions of the Act and the regulations, which should be considered in concert and not in isolation, can be accessed at [Victorian Law Today](http://www.legislation.vic.gov.au/) <http://www.legislation.vic.gov.au/>.

This is one of a series of documents prepared by Medicines and Poisons Regulation (MPR) to assist multiple or specific categories of health practitioners to understand the more common legislative requirements. Refer to the [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website for other ‘Documents to print or download’ and for a link to the Poisons Standard, which contains details of poisons schedules plus labelling and packaging requirements.

# Clarifying the meaning of key terms

The following explanations are provided in relation to terms that are in common use or contained within the Act and regulations.

* ‘**Administer**’ means to personally introduce a medicine to a person’s body or, in some cases, to personally supervise its introduction.
* ‘**Supply**’ means to provide a medicine that is to be used or administered at a later time.
* ‘**Dispense**’ is a commonly used term that is **not interchangeable** with ‘supply’. For example, a pharmacist might dispense a prescription with the intention of supplying the medicine but the supply might not occur until a later time (if at all). To avoid misunderstandings, the terms ‘administer’ and ‘supply’ are used in the legislation.
* ‘**Prescribe**’ is a term that commonly relates to the action of a practitioner who authorises treatment that may be carried out by another person. The 2017 Regulations describe this action in accordance with the three different mechanisms by which the treatment may be authorised; namely **‘issuing a prescription**’, ‘**writing a chart instruction**’ and ‘**authorising administration**’.
* In Victoria, the term ‘**drug of dependence**’ is used to describe substances, listed in Schedule 11 of the Act, which are known to be subject to misuse and trafficking. Note: The term is not limited to Schedule 8 and 9 poisons as some Schedule 4 poisons (e.g. benzodiazepines, pseudoephedrine, testosterone and other anabolic steroids) are also classified as drugs of dependence. However, most regulations relate primarily to whether a drug is a Schedule 4 or Schedule 8 poison (rather than a drug of dependence).
* The term ‘**as soon as practicable**’, where it appears in the legislation, is not to be interpreted as ‘when it is convenient’; for example, a person who is required to forward a document ‘as soon as practicable’ is required to do so not later than would be achieved by forwarding the required document via Australia Post.

# All reasonable steps

The requirement for a health practitioner to take ‘**all reasonable steps**’ occurs in many regulations.

* It is a subjective phrase that is intended to provide flexibility of approach according to the circumstances.
* It is important that health 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 health practitioners to take ‘all reasonable steps’ (e.g. regulations 17(c) and 17(e) for medical practitioners; regulation 51 for pharmacists); 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 corresponding profession, would take if put in that situation.

## After hours

The steps that might reasonably be taken during typical opening hours on a weekday are likely to differ from the steps that might be reasonably available to a practitioner after hours, on weekends or on public holidays.

## Quantity and repeats

Whereas a practitioner might be considered to have taken all reasonable steps to justify prescribing a minimal quantity of a drug of dependence; 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

Health practitioners, who are authorised to issue prescriptions for a drug of dependence, 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.

**Note**: If a prescription is issued for a Schedule 8 poison or another monitored supply poison, the prescriber must also include the patient’s date of birth on the prescription.

## 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 in order to:**
	+ review records relating to recent dispensing events of monitored poisons, which have been supplied to the patient
	+ determine whether another practitioner holds a permit to prescribe Schedule 8 poisons for the patient

# Using SafeScript

**Since** 1 April 2020, medical practitioners, nurse practitioners and pharmacists have been required to take ‘all reasonable steps’ to check a patient’s SafeScript profile before issuing a prescription for (or supplying) any monitored supply poison to the patient.

## Monitored supply poisons

* all Schedule 8 medicines
* all benzodiazepines (e.g. diazepam; clonazepam)
* ‘Z-drugs’ (zolpidem, zopiclone)
* quetiapine
* gabapentin
* tramadol
* pregabalin
* codeine containing products

## Mandatory checking of the SafeScript database

The Act 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 poison – **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 an 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 poison. 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.

**Note:** practitioners using software that is integrated with SafeScript will receive red, amber or green notifications when prescribing or supplying a monitored supply poison. These notifications are designed to quickly and clearly signal to the prescriber or pharmacist:

* The level of risk that may be associated with a patient being prescribed or supplied a monitored supply poison.
* The amount of time and effort likely to be required to examine the patient’s SafeScript profile to determine whether it is safe and appropriate to prescribe or supply.

The red, amber or green notifications **must not be relied upon** when making clinical decisions on whether it is safe and appropriate to prescribe or supply – the patient’s SafeScript profile **must** be checked **on each occasion** prior to prescribing or supplying a monitored supply poison unless a specific exception is applicable.

## Specified exceptions to mandatory checking of SafeScript

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

**A pharmacist** is not required to check SafeScript before supplying a monitored supply poison 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** are not required to check SafeScript before prescribing or supplying a monitored supply poison 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** are not required to check SafeScript before prescribing or supplying a monitored supply poison 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 poison is intended to provide palliative treatment.

# Patient delivered partner therapy (PDPT)

Medical practitioners and nurse practitioners who prescribe or supply azithromycin, a Schedule 4 poison, to provide patient delivered partner therapy for a microbiologically confirmed chlamydia infection, generally will be considered to have satisfied the requirement (of regulations 17(c), 20(c), 36(b) or 39(b)) to take **‘all reasonable steps’** to ensure a therapeutic need exists, if they provide therapy in accordance with the [Patient Delivered Partner Therapy Clinical Guidelines](https://www2.health.vic.gov.au/about/publications/policiesandguidelines/pdpt-clinical-guidelines) <<https://www2.health.vic.gov.au/about/publications/policiesandguidelines/pdpt-clinical-guidelines>>.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

50 Lonsdale Street

Melbourne, 3000

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

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

* For information and details, relating to current, recent and pending Schedule 8 permits, please refer to the patient’s profile on the SafeScript database.
* For queries relating to the Act or regulations, please:
	+ refer to the ‘Documents to print or download’ that are available on the MPR website (see below); or
	+ if you are unable to address your query by referring to those documents, forward your query via e-mail to dpcs@health.vic.gov.au

## 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 recording
	+ Prescribing
	+ Criteria for lawful prescriptions
	+ All reasonable steps and other key terms
	+ Schedule 2 and 3 poisons
* Summaries that are specific to individual categories of health practitioner:
	+ Medical practitioners
	+ Pharmacists
	+ Nurses and midwives
	+ Nurses and midwives with registration endorsement (e.g. nurse practitioners, authorised midwives, etc.)
	+ Dentists (and other dental practitioners)
	+ Optometrists (and orthoptists)
	+ Podiatrists
	+ Veterinary practitioners

## Other possible sources of information

### Australian Health Practitioner Regulation Agency (Ahpra)

Web: [www.ahpra.gov.au](http://www.ahpra.gov.au)

### Drug and Alcohol Clinical Advisory Service (1800 812 804)

Registered health practitioners (only) may phone the **DACAS** at any time to seek **clinical advice** from specialists or other practitioners, who have been specially trained to provide advice in relation to pain, addiction and mental health issues, and for assistance with developing safe treatment plans, gradual dose tapering and alternative treatment options.

### Direct Line (1800 888 236)

* 24-hour confidential **drug and alcohol counselling** serviceforpatients
* 24-hour advisory service about available **treatment facilities** for patients, family or health practitioners

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