

SCHEDULE 8 PERMIT and NOTIFICATION REQUIREMENTS from 1 March 2009

This summary has been prepared by the Drugs and Poisons Regulation Group (DPRG) to assist in understanding permit and notification requirements that apply from 1 March 2009 when prescribing Schedule 8 poisons and other drugs of dependence. Refer to the Drugs, Poisons and Controlled Substances Act 1981 and Regulations 2006 (at www.legislation.vic.gov.au) for full details. The DPRG website (www.health.vic.gov.au/dpu) contains summaries of other key requirements plus a link to the Commonwealth standard (or "Poisons Standard"), which contains the full list of scheduled poisons.

Note: Failure to comply with Victorian legislation renders a person liable to prosecution – regardless of whether (or not) a drug is prescribed as a Pharmaceutical Benefit.

Schedule 8 poisons

Schedule 8 poisons (labelled *Controlled Drug*) have stricter legislative controls than other "prescription-only medications"; they include pethidine, morphine (Kapanol, MSContin, Sevredol), oxycodone (OxyContin, Oxynorm, Endone), hydromorphone (Dilaudid), methadone (Physeptone), flunitrazepam (Hypnodorm), fentanyl (Durogesic), buprenorphine (Subutex, Suboxone, Norspan), dexamphetamine, methylphenidate (Attenta, Concerta, Ritalin).

Drug-seeking behaviour

A patient with a **valid** therapeutic need for Schedule 8 poisons **should** have a principal medical practitioner to monitor and manage his/her medication regimen to maximise treatment outcomes and minimise the likelihood of an iatrogenic dependence. Concurrent prescribing by other medical practitioners may be detrimental, especially if the principal prescriber is unaware of that prescribing.

Note:

- Drug-seeking behaviour is **not** limited to users of illicit drugs.
- A person with a genuine medical condition is not immune to becoming drug-dependent.
- Drug-seeking activity may be associated with diversion and sale of prescription drugs.

Permits for Schedule 8 poisons

In order to ensure Schedule 8 poisons are available to patients with genuine therapeutic needs whilst minimising the potential for concurrent prescribing and successful drug-seeking occurring, medical practitioners must obtain a permit (section 34A(1)) from DPRG:

- **Before** treating a **drug-dependent person** with any Schedule 8 poison. (Permits to prescribe pharmacotherapy to treat opioid-dependence may be issued to medical practitioners who have been specifically approved by the DPRG).
- To treat a person, who is **not drug-dependent**, with any Schedule 8 poison for a **period greater than 8 weeks** (Refer to page 2 for further clarification).

Note:

- **Most medical practitioners** are still required to obtain a permit **before prescribing** dexamphetamine, methylphenidate or methadone for any person.

- A PBS Authority prescription for a Schedule 8 poison indicates that the Commonwealth will subsidise the cost of the medication; **permit requirements are still applicable.**

Clarifying “The 8-Week Rule”

The 8-week period (before obtaining a permit to treat a person who is **not drug-dependent**) allows a medical practitioner to **initiate** treatment with a Schedule 8 poison without delay. **Note:** The 8-week period relates to the duration of treatment and **not** the dates of consultations. A single prescription, for sufficient medication to provide treatment for more than 8 weeks, would require a permit.

Patients already being treated with Schedule 8 poisons

To address circumstances where a patient might be receiving or seeking treatment from multiple practitioners, the 8-week period now includes any preceding period of treatment by other medical practitioners.

A medical practitioner who considers it necessary to prescribe a Schedule 8 poison for a person (who is **not drug-dependent**) must immediately apply for a permit if there is reason to believe that his/her prescription will result in the patient being treated for a continuous period greater than 8 weeks when the preceding period of treatment is taken into consideration. This provision is intended to include patients (with or without documentation) who:

- claim to be relocating from another clinic or visiting from a distant or interstate location
- claim that the regular treating practitioner is unavailable
- are being treated by multiple practitioners (none of whom hold a permit) at the same clinic

Although a permit application must be submitted immediately, to avoid delaying treatment for a genuine patient, a medical practitioner is authorised to continue treating the patient until the outcome of his/her permit application has been determined.

Methadone, dexamphetamine and methylphenidate

Although there are some exceptions (see below) to the requirement to hold a permit, **most medical practitioners** are still required to obtain a permit **before prescribing** dexamphetamine, methylphenidate or methadone for any person.

EXCEPTIONS TO PERMIT REQUIREMENTS

Cancer pain and childhood ADHD

Under certain conditions and circumstances a permit is not required to treat a person (who is **not drug-dependent**) for cancer pain or childhood attention deficit disorder **provided** the medical practitioner gives written notice to DPRG in the required form - by submitting the permit application form and completing section 3.

General exceptions – prisons, residential aged care services, in-patients

In circumstances where a person is confined and not personally managing their medications, the risk of concurrent prescribing is significantly reduced. Accordingly a permit is not required to prescribe Schedule 8 poisons for prisoners being treated in a **prison**, residents being treated in a **residential aged care service** and patients receiving **in-patient treatment in a hospital** (not including day procedure centres).

Multi-practitioner clinics

In recognition of the fact that more than one medical practitioner at a clinic might be involved in the management of some patients, each practitioner is not required to obtain a permit provided a valid permit is held by one practitioner at the clinic **and** the prescribing is consistent with and does not exceed any limits of the permit.

Note: To ensure compliance it is recommended that details of permits, including maximum dosage plus expiry or cancellation dates, are prominently displayed within patient records.

Exceptions relating to methadone or dexamphetamine and methylphenidate

The **additional** permit requirement, to obtain a permit before prescribing methadone, does not apply where a medical practitioner is treating a person who is an in-patient of a hospital, a patient at an oncology clinic, a patient under the care of a palliative care service or a patient at a pain clinic at a hospital.

The **additional** permit requirement, to obtain a permit before prescribing dexamphetamine or methylphenidate, does not apply where a medical practitioner is a paediatrician or psychiatrist who is treating a person with attention deficit disorder.

Note: A permit to prescribe any of these three drugs is still required to treat a drug-dependent person or to provide treatment for more than 8 weeks – unless another exception applies.

NOTIFICATION OF A DRUG-DEPENDENT PERSON

The legislation still requires a practitioner to notify the DPRG when he/she has reason to believe that a patient is a drug-dependent person if—

- The patient requests or seeks prescription of a Schedule 8 poison or a Schedule 4 poison which is also a drug of dependence; or
- The practitioner intends to treat or is treating the patient with a Schedule 8 poison or a Schedule 4 poison which is also a drug of dependence.

For further information about suspected drug-seeking patients or permit requirements, contact the **DPRG Help Line - 1300 364 545** (to avoid delays - **select option 1**).

Further information and application or notification forms are also available from the DPRG website
<http://www.health.vic.gov.au/dpu>

Department of Health

Drugs and Poisons Regulation Group
GPO Box 4057,
Melbourne 3001

Tel: 1300 364 545
Fax: 1300 360 830