Policy for issuing Schedule 8 permits

health

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The purpose of this document is to inform prescribers of the matters the Department of Health considers when assessing applications for permits to prescribe Schedule 8 poisons.

This document has been endorsed by the Department of Health's Chief Clinical Advisor – Addiction Medicine.

Introduction

The *Drugs, Poisons and Controlled Substances Act 1981* sets out certain circumstances when a registered medical practitioner or nurse practitioner must apply for a permit to prescribe a Schedule 8 poison. These are substances which should be available for use but require restrictions on supply to minimise abuse, misuse and dependence.[1]

(The Act defines "Schedule 8 permits" as meaning permits to administer, supply or prescribe a Schedule 8 poison issued by the Secretary under section 34A.)

Generally, a permit is required before any treatment of a drug dependent person, before any treatment with methadone, nabiximols or a psychostimulant drug, or when treatment with a Schedule 8 poison exceeds eight weeks (includes any period of treatment provided by another practitioner). There are exceptions to these requirements however. It is the responsibility of the practitioner to know if they are required by the Act to hold a permit in a particular case.

This document sets out the policies of the Department of Health when assessing an application from a practitioner for a permit to prescribe a Schedule 8 poison. Information about a practitioner's legislative obligations, including downloadable copies of this and other Departmental policies and other information about drugs and poisons controls in Victoria are available from the Drugs and Poisons Regulation (DPR) website at www.health.vic.gov.au/dpcs, or by request via email at dpcs@health.vic.gov.au.

The Department has also developed advice sheets relating to different aspects of treatment with Schedule 8 poisons, including recognising behaviours indicative of substance abuse. These advice sheets can also be obtained from the DPR website.

Reasons for issuing permits

The requirement for a permit recognises the special risks associated with Schedule 8 poisons, and the consequent need to coordinate treatments between practitioners to avoid concurrent treatment of a patient with the same or similar Schedule 8 poison by multiple practitioners. The intention is to maximise patient safety and to minimise the risk of patients developing or maintaining dependence and to avoid diversion of licit drugs for illicit purposes.

When permit applications are received, they are registered in a database. The database contains a history of current or past permits, and also records mandatory notifications submitted by medical practitioners, pharmacists and other health practitioners, such as notifications of drug dependency. Relevant information contained in the database may be provided to the practitioner making an application in order to assist the practitioner make safe, legal and effective treatment decisions.

The Department does not make clinical assessments of particular cases and does not offer clinical advice to practitioners. The issuing of a permit is not an endorsement of treatment. The responsibility for assessing the clinical appropriateness of treatment of a patient always rests with the practitioner.

Practitioners may refer to appropriate clinical guidelines for clinical advice when considering treatment with a Schedule 8 poison. Such guidelines, which are referenced in this document, include the National Prescribing Service (NPS), Hunter New England Area Health, the Therapeutic Guidelines, the Australian Medicines Handbook (AMH) and the Australian Pain Society.

Further to these guidelines, the Chief Clinical Adviser – Addiction Medicine or other medical officers within the Department may also provide advice when applications are processed, when permits are issued or revoked, or when applications are refused.

This policy outlines what actions will take place when an application is received. Practitioners making applications may contact DPR by email at dpcs@health.vic.gov.au or telephone on 1300 364 545 to discuss a particular case with a Drugs and Poisons Officer if necessary.

General requirements

(From herein, a registered medical practitioner or nurse practitioner applying for a permit will be referred to as an "applicant".)

Circumstances where a Schedule 8 permit is likely to be issued

Generally, a permit will be issued to the applicant without a request for further supporting information, where:

i. the drug has an approved indication (by the Therapeutic Goods Administration) for the specified diagnosis for the patient, or where there is documented evidence for its therapeutic use for that diagnosis, and
ii. the dose is within accepted doses ranges as recommended in clinical guidelines, and
iii. there is no other practitioner holding a permit to treat to treat the patient, and
iv. there is no record of notifications of drug dependence, aberrant drug-related behaviour or suspected unlawful behaviour associated with prescription medications received for the patient.

Circumstances where further information will likely be requested before a permit is issued

A permit for the same or similar drug will generally not be issued to more than one practitioner concurrently unless it is clear that adequate communication between the practitioners has occurred and ongoing treatment is to be coordinated.

Where there is information about past permits or notifications for that patient or other information provided by other sources that might be relevant to the application, this information may be provided to the applicant. Where there is:

i. a history of permits for opioid replacement therapy (ORT), or
ii. notifications of drug dependency, aberrant drug-related behaviour or suspected unlawful behaviour associated with prescription medications, or
iii. concern about an aspect of the application that may compromise the safety of the patient, e.g. doses exceeding recommendations in clinical guidelines,

the applicant will normally be requested to provide supporting information for a permit to be issued. Applications may be refused if the additional information requested is not provided.

Incomplete permit applications

It is a regulatory requirement that certain information must be provided when applying for a permit to prescribe a Schedule 8 poison. Incomplete applications cannot be processed until the required information is provided by the applicant.

In the case of applications for ORT permits, it essential for the safe treatment of patients transferring from one practitioner to another that the drug, dose and date of last dose be obtained by direct contact with the most recent dosing point. Where possible, the previous practitioner should also be contacted by the applicant to be advised that the patient has transferred, and to seek any relevant information that may assist with treatment.

When an incomplete permit application is received, the applicant will be requested to resubmit a completed application. If the required information is not provided within:

i. 10 working days from the date of the request for Schedule 8 permit applications, or
ii. 3 days from the date of the request for ORT permit applications,

the applicant will be advised that the application has not been processed. A new application will be necessary if a permit is still required.

It is an offence to deliberately provide false information in relation to an application for a permit.

Requirements for specific Schedule 8 poisons

Specific requirements for particular Schedule 8 poisons are further described in this document.

1. Applications for opioids

Before prescribing opioids

The *Therapeutic Guidelines: Analgesic* recommends before considering treatment with an opioid, that a comprehensive assessment is essential, and nonpharmacological options should be explored before starting pharmacological therapy. A multidisciplinary approach should be taken when assessing the patient.[2]

Patient assessment should also include whether aberrant drug-related behaviours are present. It is strongly recommended that a screening tool, such as the Opioid Risk Tool[3], be used to assess the potential for opioid misuse.

Practitioners must be able to recognise problematic behaviour that is symptomatic of substance abuse disorder, and be equipped to manage it when prescribing opioids, or know when to seek advice from experienced colleagues or medical specialists.

The NPS recommends that a pain management plan should be formulated and discussed with the patient before deciding to prescribe opioids.[4] This should include defining the goals of therapy, setting an appropriate treatment timeframe, establishing a review process with colleagues or a specialist to regularly assess treatment outcomes and appropriateness of ongoing treatment, and informing the patient of his/her responsibilities to adhere to the treatment plan.

In view of these recommendations, it is reasonable to expect applicants to have formulated a pain management plan when deciding to prescribe opioids. Further, confirmation that a pain management plan has been formulated when assessing an application may be requested. Failure to provide confirmation of a pain management plan may result in an application being refused.

Concurrent prescribing

The Australian Pain Society advises that it is important that only one practitioner prescribes opioids for a patient and assesses the response.[5] Where a current permit is held by another practitioner, the applicant will be advised to make contact with that permit holder to coordinate treatment. It is highly unlikely that a permit would be issued to treat the same patient with an opioid to more than one practitioner at a time. An exception might be made where there is close cooperation between practitioners. If more than one permit is to be issued, it is the responsibility of the applicants to demonstrate that adequate consultation and coordination will be in place during the period of treatment.

Use of opioids for chronic non-malignant pain

Current evidence does not support the long-term efficacy and safety of opioid treatment for chronic non-malignant pain. There is growing evidence of harm to both individuals and society from long term opioid use.[6]

The NPS advises that specialist advice should be sought for patients requiring repeated dose escalations or higher doses of opioids. The NPS also refers to the Hunter New England Area Health dose recommendations (see Table 1) for maximum opioid doses that should not be exceeded without specialist advice.[4]

Table 1:
Recommended maximum opioid doses[6,7]

Generic name	Recommended maximum dose
hydromorphone	20mg daily
methadone	30mg daily
morphine	100mg daily
oxycodone	60mg daily
tapentadol	250mg daily
buprenorphine patch	40mcg/hr weekly
fentanyl patch	25mcg/hr every three days

Additional supporting information may be sought from applicants about the level of specialist support they have obtained when considering long term opioid treatment.

In view of the Hunter New England Area Health recommendations, permit applications for higher doses of opioids (i.e. significantly above the recommended maximum dose) will generally require evidence that recent supportive advice has been obtained from a specialist in a specialty relevant to the patient's medical condition for a permit to be issued. Without such evidence, applications may be refused.

Patient history of ORT permits or notifications

The *Therapeutic Guidelines: Analgesic* provides advice to practitioners about the use of opioid analgesics in opioid dependent patients or patients with substance use disorder. Due to the complexities of treating opioid dependent patients with opioids, practitioners should seek early advice from a pain or addiction medicine specialist.[2]

Applications for permits to treat patients with a history of drug dependency will generally require evidence that recent supportive advice has been obtained from a specialist in a specialty relevant to the patient's medical condition for a permit to be issued. Without such evidence, applications may be refused.

Specific opioids, formulations, or conditions

a) Codeine

The NPS advises that codeine has a limited role in the treatment of chronic pain, and is a short-acting opioid suitable only for mild to moderate pain.[4] The AMH states that the maximum daily dose of codeine is 240mg daily, and advises that an alternative opioid should be considered if this dose is reached.[7]

Permit applications for doses of codeine greater than 240mg daily will generally require evidence that recent supportive advice has been obtained from a specialist in a specialty relevant to the patient's medical condition for a permit to be issued. Without such evidence, applications may be refused.

b) Tapentadol

Current experience with use of tapentadol in Australia is limited.[2] Total daily doses of tapentadol greater than 500mg have not been studied and are not recommended.[9]

Permit applications for doses of tapentadol greater than 500mg daily will generally require evidence that recent supportive advice has been obtained from a specialist in a specialty relevant to the patient's medical condition for a permit to be issued. Without such evidence, applications may be refused.

c) Injectable opioids for chronic pain

The Australian Pain Society advises that: *"There is agreement internationally and within Australia that intra-muscular opioids should play no part in the treatment of chronic nonmalignant pain. In particular intra-muscular pethidine should be avoided"*.[5]

Sustained release oral or transdermal opioid preparations are the formulations of choice in patients with chronic non-malignant pain, because of their single or twice daily dosage and stable blood concentrations as a consequence of less fluctuation between peak and trough plasma levels.[4,5]

Permit applications for use of injectable opioids will generally require evidence that recent supportive advice has been obtained from a specialist in a specialty relevant to the patient's medical condition for a permit to be issued. Without such evidence, applications may be refused.

d) Opioids for migraine

Clinical guidelines recommend against the regular use of opioids for migraine. Repeated use of opioids increases the risk of dependency, medication overuse headache and hyperalgesia.[10] Further information is available from the Department's factsheet *Opioids for migraine treatment: use with extreme caution*.

Permit applications requesting use of opioids for migraine will generally require evidence that treatment is consistent with the advice outlined in the Department's factsheet for a permit to be issued. Without such evidence, applications may be refused.

2. Applications for dexamphetamine, lisdexamfetamine or methylphenidate

Attention Deficit Hyperactivity Disorder (ADHD)

Clinical guidelines recommended by the Royal Australian and New Zealand College of Psychiatrists advise that a diagnosis of ADHD should only be made by a paediatrician, psychiatrist or other appropriately qualified healthcare professional with training and expertise in the diagnosis of ADHD. Drug treatment for ADHD should be reviewed at least yearly.[11]

Permits to treat a patient with psychostimulants for ADHD will generally only be issued to neurologists, paediatricians or psychiatrists.

Permits may be issued to General Practitioners (GPs) with supporting treatment advice from the patient's neurologist, paediatrician or psychiatrist, where there is evidence of a specialist diagnosis and a review by the specialist within the last 12 months. Without such evidence, applications may be refused.

The legislation exempts paediatricians and psychiatrists treating patients under 18 years of age with a psychostimulant for ADHD from the requirement of applying for a permit. Instead, the paediatrician or psychiatrist must make a notification of treatment (a section 34D notification) by completing Section 3 of the S8 permit application form.

Narcolepsy

An initial diagnosis of narcolepsy must involve a respiratory physician or a specialist in sleep disorders.

Permits to treat a patient with dexamphetamine or methylphenidate for narcolepsy will generally only be issued to respiratory or sleep physicians.

Permits may also be issued to GPs where there is evidence of a specialist diagnosis. Without such evidence, applications may be refused.

Once narcolepsy is diagnosed, subsequent permit applications for dexamphetamine or methylphenidate will generally not require further supporting information, provided other risks to patient safety are not evident.

Other conditions

Provided there is documented evidence for its therapeutic use, permits to treat other conditions with dexamphetamine, lisdexamfetamine or methylphenidate will generally only be issued to specialists in a specialty relevant to the patient's medical condition.

Permits may be issued to GPs with supporting treatment advice from the patient's specialist, where there is evidence of a specialist diagnosis and at least yearly review by the specialist. Without such evidence, applications may be refused.

3. Applications for flunitrazepam

The AMH states that flunitrazepam is not recommended for initial drug treatment of insomnia or anxiety and misuse of the drug is common.[8]

The *Therapeutic Guidelines: Psychotropic* advises that hypnotics should only be used in the treatment of insomnia for the shortest time possible (preferably intermittently and for less than two weeks) and a definite duration of use agreed with the patient at the outset.[12] Continuous long-term use of flunitrazepam is not recommended.[13]

Permit applications for flunitrazepam will generally require evidence that recent supportive advice has been obtained from a specialist in sleep disorders or a psychiatrist for a permit to be issued. Without such evidence, applications may be refused.

4. Applications for alprazolam

The NPS recommends that the use of benzodiazepines, including alprazolam, is not recommended as first line treatment for anxiety or panic disorder. Benzodiazepine use should be reserved to the short-term for patients who have not responded to at least two other therapies (e.g. psychological therapy, antidepressants).[14]

Applications for permits to prescribe alprazolam will generally require evidence that recent supportive advice has been obtained from a specialist in a field of specialty relevant to the patient's medical condition for a permit to be issued.

Given that alprazolam is indicated for the short-term treatment of anxiety or panic disorder, support from a psychiatrist will be required. In circumstances where there are addiction-related issues with alprazolam, support from an addiction medicine specialist will be required. Without such evidence, applications may be refused.

5. Applications to treat drug dependence

An extensive evidence base exists for opioid replacement therapy with methadone syrup or buprenorphine sublingual tablet or film.[15] The Department provides advice to practitioners in its *Policy for Maintenance Pharmacotherapy for Opioid Dependence*. This policy is available from the DPR website at www.health.vic.gov.au/dpcs/pharm.htm.

The DPR website also contains links to the national clinical guidelines for methadone and buprenorphine.

Permits to treat a patient with a Schedule 8 poison for drug dependence, other than methadone or buprenorphine for opioid dependence, will generally not be issued unless supported by an addiction medicine specialist, or where treatment is part of a clinical trial with ethics approval.

6. Applications for treatment outside common medical practice

Permits for the use of Schedule 8 poisons where there is a limited evidence base, or outside common medical practice will generally not be issued unless supported by expert opinion, or where treatment is part of a clinical trial with ethics approval.

Other resources

Clinical advice for health professionals

To obtain clinical advice from addiction medicine consultants, health professionals may phone the Drug and Alcohol Clinical Advisory Service (**DACAS**) on 1800 812 804.

Counselling and advice for patients

For 24-hour confidential drug and alcohol counselling and treatment information, patients, family or health professionals may phone **DirectLine** on 1800 888 236.

References

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5. Graziotti PJ, Goucke CR. The use of oral opioids in patients with chronic non-cancer pain: Management strategies. Med J Aust. 1997:167:30.
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15. National Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014).

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