

Guidelines for Prescribers Prescribing Controlled Medicines

These guidelines have been prepared by the Health Protection Service to assist prescribers in understanding their legislative requirements when prescribing controlled medicines in the ACT.

The information has been consolidated from the *Medicines, Poisons and Therapeutic Goods Act 2008* (Act) and the *Medicines, Poisons and Therapeutic Goods Regulation 2008* (Regulation). Prescribers are obliged to comply with the Act and Regulation and failure to do so may render a person liable for penalties. Copies of the legislation may be found at www.legislation.act.gov.au.

A controlled medicine is defined as any medicine listed in Schedule 8 of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP).

Approvals to prescribe controlled medicines

In order to ensure that controlled medicines are available to patients with genuine therapeutic needs whilst minimising the potential for concurrent prescribing and successful drug-seeking behaviour, a prescriber in the ACT must have approval under the Regulation to prescribe a controlled medicine.

An approval may take the form of either a Chief Health Officer (CHO) approval or Standing approval.

Prescriptions for controlled medicines must include the relevant approval details in order to be valid (other than for inpatients). Prescribers that fail to seek approval where required may face disciplinary or enforcement action, including being charged with an offence under the Act for which significant penalties are attached. Similarly, pharmacists that dispense a controlled medicine where the necessary approval is not in place may also face disciplinary or enforcement action, including being charged with an offence under the Act for which significant penalties are attached.

An approval is an additional requirement under ACT law and does not relate to PBS Authorities. A PBS Authority indicates that the Commonwealth Government will subsidise the cost of the medicine, however it is not a legal authority to prescribe it in the first place.

Chief Health Officer approvals

A prescriber must obtain a CHO approval to prescribe a controlled medicine for each patient when:

- they prescribe or intend to prescribe a controlled medicine for more than 2 months, or
- the patient has been prescribed a controlled medicine within the previous 2 months, or
- they believe that the patient is drug-dependent.

Applications for CHO approvals may be forwarded to the Health Protection Service.

Approved applications will be issued with a CHO approval number, which must be annotated on the prescription as 'CHO approval number' followed by the identifying number for the approval.

Where more than one doctor at a medical clinic is involved in the management of a patient, each doctor may prescribe under a CHO approval in place for another doctor at the clinic, provided the prescribing is consistent with and does not exceed any limits or condition of the approval.

Standing approvals

A prescriber does not need to obtain a CHO approval when a standing approval is in place.

A standing approval means that a prescriber is automatically authorised under the Regulation to prescribe a controlled medicine in certain circumstances.

A standing approval to prescribe a controlled medicine applies where:

- the patient is an in-patient at a hospital, including a hospice, or
- a CHO approval is not required; i.e. the prescriber believes on reasonable grounds that the patient is not drug-dependent, and the patient has been not been prescribed a controlled medicine within the preceding 2 months and they prescribe or intend to prescribe the controlled medicine for less than 2 months.
- a doctor who works at a hospital, correctional centre, a Children and Young People detention centre, or an opioid dependency treatment centre operated by the Territory prescribes methadone or buprenorphine to a drug-dependant person who is a patient of that institution for up to 72 hours. However, the doctor must apply for CHO approval within 72 hours.

The general two month period allowed prior to seeking CHO approval for non drug-dependent patients allows a prescriber to initiate therapy without delay, or to allow sufficient time for dose titration prior to seeking CHO approval.

The two month period relates to the duration of treatment and includes any preceding period of treatment by another prescriber.

Prescriptions must still be annotated with details of the standing approval as appropriate (other than for inpatients); i.e. the words 'Standing short term approval' or 'Standing opioid dependency approval'.

Interstate prescriptions

Interstate practitioners are able to prescribe controlled medicines in accordance with the laws of the State or Territory in which they are practicing. However, controlled medicines will not be dispensed in the ACT unless they have the relevant approvals.

If interstate prescribers believe that a script for a controlled medicine they prescribe will be dispensed in the ACT, they will need to obtain CHO approval where required and ensure that the prescription includes the relevant approval details.

Similarly, ACT prescribers who are aware that their patient intends to have a prescription they have written dispensed in another State or Territory, should comply with the laws of the State or Territory in which the prescription will be dispensed.

Drug-dependent patients and Opioid Maintenance Treatment

A valid CHO or standing approval must be in place for all prescriptions for a controlled medicine where the patient is deemed to be drug-dependent.

A drug-dependent person in relation to a controlled medicine is defined by the Act as:

‘a person with a condition who, as a result of the administration of a controlled medicine or prohibited substance, demonstrates, in relation to the person’s use of the medicine or substance, impaired control or drug-seeking behavior that suggests impaired control and who, as a result of the cessation of the administration of the medicine or substance, is likely to experience symptoms of mental or physical distress or disorder.’

CHO approval to prescribe a controlled medicine for the treatment of drug dependence will only be granted to prescribers for recognised treatments, currently methadone and buprenorphine. These approvals will only be granted in accordance with the legislation and the ACT Opioid Maintenance Treatment Guidelines (OMT Guidelines). Copies of the OMT Guidelines may be found at www.health.act.gov.au/health-services/community-health/community-health-services/alcohol-other-drugs/opioid-maintenance-treatment.

In accordance with the OMT Guidelines, doctors (except those working at nominated ACT Government facilities) are also required to be endorsed to treat drug-dependency where they wish to induct clients onto therapy or prescribe for more than 5 stable clients at a time. In order to become endorsed, doctors need to complete an approved training program and undertake a period of placement at the ACT Alcohol and Drug Program. Applications for endorsement may be forwarded to the Health Protection Service.

A community pharmacy must also be licensed as an Opioid Dependency Treatment Centre to dispense opioid maintenance treatment in the ACT.

Applications for CHO approval that require special consideration

Amphetamines for Attention Deficit Hyperactivity Disorder

Approvals to prescribe amphetamines for the treatment of ADHD and adult ADHD will only be issued in accordance with the criteria endorsed by the Medicines Advisory Committee. See “Criteria for the issue of approvals to prescribe amphetamines for Attention Deficit Hyperactivity Disorder (ADHD)”.

Palliative Care Patients

Approvals may be granted for up to twelve months for the treatment of a terminal illness when diagnosed by a specialist; where the controlled medicine is for therapeutic purposes only; and where life expectancy is less than one year. If granted, the approval allows you to prescribe morphine and/or oxycodone in all forms and strengths for 12 months.

Flunitrazepam

Approvals for flunitrazepam will only be granted for continuing therapy in ageing patients who have been stabilised on the medicine. New approvals will only be granted in exceptional circumstances with documented support from a specialist.

Regular controlled medicine injections for chronic use

Applications are unlikely to be granted for the prescription of regular injections of a controlled medicine for chronic pain conditions without the documented support of an appropriate specialist or pain clinic.

Voluntary Undertakings

The Voluntary Undertaking (VU) scheme is a non-legislated scheme unique to the ACT whereby a patient agrees to have their prescriptions written by only one doctor, and dispensed from only one pharmacy. The VU scheme was designed to assist doctors and pharmacists in the management of their patient(s) whom they suspect may have problems with drug dependency.

The VU scheme is most commonly used for managing benzodiazepine dependency, however may also be used for a controlled medicine. However this does not replace the need for a prescriber to seek CHO approval where required.

References

Medicines, Poisons and Therapeutic Goods Act 2008
Medicines, Poisons and Therapeutic Goods Regulation 2008
ACT Opioid Maintenance Treatment Guidelines

Related documents

All related documents may be found at
www.health.act.gov.au/pharmaceuticalservices.

Criteria for the issue of approvals to prescribe amphetamines for Attention Deficit Hyperactivity Disorder (ADHD)
Application for Approval to Prescribe a Controlled Medicine
Application for Approval to Prescribe a Controlled Medicine for Use in an Opioid Dependency Treatment Program
Endorsement to treat drug-dependency application
Guidelines for Pharmacists Dispensing Controlled Medicines
Voluntary Undertakings- Protocol for Management

Acknowledgement

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Further information

Pharmaceutical Services
Health Protection Service
Howard Florey Centenary House, 25 Mulley St, Holder ACT 2611
Locked Bag 5005 Weston Creek ACT 2611
Email: hps@act.gov.au website: www.health.act.gov.au
Ph 02 6205 1700 or 02 6205 0998 Fax 02 6205 0997