

Regulatory Framework for Controlled Medicines Approvals

This information is for prescribers and pharmacists involved in the prescription and supply of controlled medicines in the ACT.

This document has been prepared for information only and should be read in conjunction with the *ACT Controlled Medicine Prescribing Standards* (available at <http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services>) and the Medicines, Poisons and Therapeutic Goods Regulation 2008 (at www.legislation.act.gov.au) for detailed information regarding the regulatory framework.

Controlled Medicines

Controlled medicines are prescription medicines that are associated with an increased risk of misuse, abuse, dependency or diversion. These medicines are subject to greater regulatory control to minimise their potential harms to individuals and public health.

Controlled medicines are listed under Schedule 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*. Common types of controlled medicines include potent opioids such as morphine, psychostimulants such as dexamphetamine and some benzodiazepines such as alprazolam. The ACT adopts the SUSMP and regulates the supply of controlled medicines under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

In order to minimise the public health risks associated with controlled medicines, prescribers need to hold a valid approval to prescribe a controlled medicine for each patient in the ACT.

Prescribers may apply to the Chief Health Officer for approval to prescribe a controlled medicine.

Regulatory Framework

The regulatory framework that exists for controlled medicines and the capacity to monitor controlled medicines supply via the DAPIS database gives the ACT a unique opportunity to be a leader in reducing the harms associated with the abuse, misuse and diversion of these medicines.

In 2016, ACT Health developed amendments to the Medicines, Poisons and Therapeutic Goods Regulation 2008 to improve the regulatory framework and reduce the burden placed on doctors, pharmacists and patients in the supply of controlled medicines.

Prescribers are able **seek approval to prescribe a therapeutic class of controlled medicine(s)** for a patient through a category approval system, as determined by the Chief Health Officer (CHO) or they can apply **for approval for each drug, form and strength**. Additionally, prescribers are **no longer required to annotate the CHO approval details** on the prescription.

Controlled Medicine Approval by Category

Prescribers can apply prescribers to seek approval to prescribe a therapeutic class of controlled medicine(s) for a patient through a category approval system. The category approvals will enable prescribers to increase or decrease doses and switch between medications within the approved limits of the category without having to seek CHO approval each time.

Category 1 – Controlled medicine to treat a person with chronic (non-cancer) pain.

Category 2 – Controlled medicine to treat a person with pain directly attributed to:

- active malignancy or life limiting disease state; or
- on a case-by-case basis; and
- where the prognosis might be reasonable considered to be expected to be 12 months or less.

Category 3 - Controlled medicine to treat a person with drug-dependency.

Category 4 - Controlled medicine to treat a person with a licensed indication or severe insomnia.

Category 5 - Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder (ADHD).

To determine if a patient is eligible for category approval please refer to the *ACT Controlled Medicine Prescribing Standards*.

Controlled Medicine Approval by Drug

Prescribers have the option to apply for approval by drug, form and strength if they would prefer or if the patient isn't eligible for category approval.

DAPIS Reference Number

For each approval prescribers will be issued a DAPIS reference number. There is no requirement to annotate this number on the prescription; however it is recommended that prescribers hold a record of the DAPIS reference number on the patients file.

More information

For further information, please see the *ACT Controlled Medicine Prescribing Standards*, visit www.health.act.gov.au/pharmaceuticalservices or contact the Pharmaceutical Services Section of the Health Protection Service on hps@act.gov.au or (02) 6205 0998.

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