

Prescribing and dispensing regulated restricted drugs

Fact sheet

Purpose

This fact sheet provides information on the requirements for prescribing and dispensing regulated restricted drugs.

Background

In Queensland, the Health (Drugs and Poisons) Regulation 1996 (HDPR) places controls on the supply and use of medicines to ensure that they are used safely and effectively. The HDPR places additional controls on the supply of certain substances, specified in Appendix D of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), where, for example, there are specific health risks that may be mitigated by restricting availability through specified specialist medical practitioners.

Regulated restricted drugs

Regulated restricted drugs (listed below in Table 1) include human follicle stimulating hormones, substances to stimulate ovulation, and substances that can cause birth defects and other serious side effects.

Table 1: Regulated restricted drugs

- Clozapine
- Dinoprost and Dinoprostone
- Clomifene, Cyclofenil or another substance specifically prepared to stimulate ovulation
- Luteinising Hormone, Urofollitropin (human follicle-stimulating hormone)
- Acetretin, Etretinate, Isotretinoin (for human oral use) and Tretinoin (for human oral use)
- Bexarotene
- Thalidomide
- Bosentan
- Teriparatide

Prescribing regulated restricted drugs

Requirements for prescriptions

All prescriptions for regulated restricted drugs must state the word “Approved”. In addition, a prescription for a regulated restricted drug is only valid where the address of the authorised prescriber on the prescription is in Queensland.

Penalties apply for improperly making prescriptions for regulated restricted drugs.

Who can prescribe regulated restricted drugs?

Prescribing of regulated restricted drugs is typically limited to selected specialists (and registrars training to become a relevant specialist, working directly under the supervision of a specialist) – see Appendix 1 below for a table of specialists authorised to prescribe, obtain or dispense specified regulated restricted drugs.

Non-specialist prescribers require an approval for therapeutic use of regulated restricted drugs from Queensland Health, except in the following circumstances:

- to prescribe isotretinoin or tretinoin, if the isotretinoin or tretinoin is in **non-oral form** (i.e. gels, creams); or
- for a doctor who dispenses, prescribes, sells or uses teriparatide under the supervision of a relevant specialist, where a patient has recently been assessed by a relevant specialist as having a therapeutic need and the patient lives in a remote place and cannot access the services of the specialist.

How to obtain an approval to prescribe regulated restricted drugs?

Prescribers seeking authority to prescribe regulated restricted drugs should complete and submit the [application form](#) to Queensland Health. There are some restrictions regarding who may apply, the supervision or shared care requirements that must be in place, and the location of the patient; these are:

Clozapine

- Prescribers may apply for an approval to prescribe clozapine in the community, under the supervision of a psychiatrist, but only for maintenance therapy in the treatment of schizophrenia.
- As part of the shared care arrangement, the prescriber receives training from a clozapine coordinator and becomes responsible for some elements of the patient’s clozapine-related care, usually ordering the monthly blood tests, in addition to managing their primary care needs.
- Brand substitution is not permitted, as each brand comes with its own monitoring service (*Clozaril Patient Monitoring System (CPMS)* for Clozaril; or *ClopineCentral* for Clopine).

Acetretin, Etretinate, Isotretinoin and Tretinoin

- Only doctors may apply for an approval to prescribe, dispense, sell or use acitretin, etretinate, isotretinoin or tretinoin; and
- The doctor must be under the supervision of a relevant specialist; and

- An approval can only be granted where a patient has recently been assessed by a relevant specialist as having a therapeutic need and the patient lives in a remote place and cannot access the services of the specialist.

Other regulated restricted drugs

- Prescribers must be under the supervision of a relevant specialist.

Dispensing regulated restricted drugs

Pharmacists *do not require* an approval from the Chief Executive of Queensland Health to dispense regulated restricted drugs, however pharmacists must only dispense a prescription written by an authorised prescriber which has been properly completed (see 'Requirements for prescriptions' in section 4 above).

Penalties apply for dispensing regulated restricted drugs that do not meet these requirements.

Special requirements – dispensing clozapine

For treatment with clozapine, pharmacists must be registered with the clozapine monitoring service applicable to the brand of clozapine they wish to dispense. Pharmacists cannot substitute brands when dispensing clozapine. The two clozapine monitoring services are brand-specific, and the patient must be managed on one or the other, not both. Pharmacists should be aware of who the clozapine coordinator is for each patient, in addition to the patient's general practitioner.

How to check if a prescriber is authorised?

To check whether a prescriber is authorised to prescribe the relevant regulated restricted drugs, pharmacists can follow these steps:

1. Check the prescriber's qualifications on the script against the specialty listings found in Appendix 1 below. (*Note: A specialist physician is a separate, additional qualification from a general practitioner.*)
2. If speciality qualifications are not found or if unsure, check the prescriber's registration details on the AHPRA website <https://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx>.
3. If no specialty qualifications are found, contact the prescriber to confirm their authority (specialist qualifications or Queensland Health approval).
4. If still unsure, contact Healthcare Approvals and Regulation Unit (**HARU**) to confirm whether the prescriber has an approval granted by Queensland Health.

Obtaining regulated restricted drugs for analytical or research purposes

Additional restrictions also apply to *obtaining* regulated restricted drugs. Doctors, Pharmacists and Veterinary Surgeons wishing to access regulated restricted drugs for research or analytical purposes must apply for an [approval to use scheduled substances](#)

[for research or analytical purposes](#), however no approval is required for approved clinical trials.

Specific penalties for regulated restricted drugs

In addition to penalties that apply generally to prescribing and dispensing controlled and restricted drugs, the following specific penalties apply for regulated restricted drugs.

For prescribers

Prescribing, dispensing, supplying or using a regulated restricted drug without authority – maximum 80 penalty units (equivalent to more than \$10,000).

Improperly preparing a prescription for a regulated restricted drug (e.g. missing 'Approved') – maximum 60 penalty units (equivalent to more than \$7,500).

For dispensers

Dispensing a prescription for a regulated restricted drug from a prescriber who is not authorised to prescribe the regulated restricted drug – maximum 80 penalty units (equivalent to more than \$10,000).

Dispensing a regulated restricted drug on a prescription where the address of the authorised prescriber on the prescription is not in Queensland – maximum 60 penalty units (equivalent to more than \$7,500).

Dispensing a regulated restricted drug on a prescription that does not comply with the regulation (e.g. missing 'Approved' or 'Specified condition') – maximum 60 penalty units (equivalent to more than \$7,500).

Failure to properly cancel a prescription (that is improperly completed or prepared by an unauthorised prescriber) and send to Queensland Health within 14 days – maximum 40 penalty units (equivalent to more than \$5,000). The pharmacist may fulfil this requirement by emailing a scanned image of the cancelled prescription to HARU@health.qld.gov.au.

Further information

For information about the Pharmaceutical Benefits Scheme (PBS) and regulated restricted drugs, see <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/commonwealth-funding>.

To apply for an approval, complete an [Application for an approval for therapeutic use of regulated restricted drugs](#).

To submit completed applications, or for further information, contact:

Healthcare Approvals and Regulation Unit

HARU@health.qld.gov.au

Phone: 07 3708 5264

www: www.health.qld.gov.au/system-governance/licences/medicines-poisons/legislation-standards/medicines

Appendix 1: List of specialty areas of practice or supervision required for prescribing regulated restricted drugs

Regulated restricted drug	Specialty area of practice authorised/ required for supervision	Respiratory and Sleep Medicine	Psychiatry	Dermatology	Infectious Diseases	Haematology	Medical Oncology	Cardiology	Rheumatology	Geriatrics	Obstetrics and Gynaecology	Endocrinology	Specialist Physician
Acitretin				✓									✓
Bexarotene						✓	✓						
Bosentan		✓						✓	✓				
Clomifene											✓		✓
Clozapine			✓										
Cyclofenil or another substance specifically prepared to stimulate ovulation											✓		✓
Dinoprost											✓		
Dinoprostone											✓		
Etretinate				✓									✓
Isotretinoin (for human oral use)				✓									✓
Luteinising Hormone											✓		✓
Teriparatide									✓	✓		✓	✓
Thalidomide				✓	✓	✓	✓						✓
Tretinoin (for human oral use)				✓									✓
Urofollitropin (human follicle-stimulating hormone)											✓		✓