

OCULAR THERAPEUTIC PROTOCOL FOR THERAPEUTIC DRUG USE BY OPTOMETRISTS

OPTOMETRISTS BOARD OF QUEENSLAND

Background

Amendments were made to the Health (Drugs and Poisons) Regulation 1996 (“the Regulation”) on 24 March 2005 to allow optometrists in Queensland to use and prescribe registered restricted drugs for the treatment of ocular disorders. The amended Regulation can be found at <http://www.legislation.qld.gov.au/Legislation%20Docs/CurrentH.htm>

Section 170 (2) of the Regulation now reads:

- “To the extent necessary to practice optometry, an optometrist who has the prescribed qualifications is authorized to –
- (a) obtain a registered restricted drug; or
 - (b) possess a registered restricted drug at the place where the optometrist practices optometry; or
 - (c) if the optometrist is reasonably satisfied a person needs a registered restricted drug for a therapeutic use as part of the person’s ocular care or treatment, do any of the following *under an ocular therapeutics protocol* –
 - (i) administer or supply the drug to the person;
 - (ii) prescribe the drug for the person.”

To meet the legislative requirements of s 170 (2), this document, the ocular therapeutics protocol (“the Protocol”), has been developed by the Board. The definition of “ocular therapeutics protocol” has been inserted into Appendix 9 of the Regulation as follows:-

- “**Ocular therapeutics protocol** means a document approved and published by the Optometrists Board of Queensland stating -
- (a) the circumstances in which, and conditions under which, an optometrist may administer, supply or prescribe a restricted drug; and
 - (b) the qualifications that an optometrist must attain before doing a thing mentioned in paragraph (a).”

This Protocol (which includes the “clinical pathways” **see 2.7**) provides the framework for the professional use of prescription medications by optometrists in Queensland. Over time, as available prescription drugs and standards of care evolve, the Protocol will be reviewed with the aim of ensuring it continues to be consistent with current knowledge and practice. Without appropriate training this Protocol is insufficient to successfully treat ocular disease. The clinical pathways are intended as guidelines and general principles to assist the optometrist in safely and effectively using certain drugs, they do not take the place of skilled clinical judgment.

This Protocol was developed using various sources including the Optometrists Registration Board of Victoria's "Protocols and guidelines for therapeutic drug use by endorsed optometrists" August 2003, the Optometry Association Australia Therapeutic Competencies 2003 and the Optometry Council Guidelines on Accrediting Postgraduate Therapeutics Training. It was agreed that clinical pathways summarizing treatment of the most common ocular diseases would be developed by the Queensland University of Technology, School of Optometry ("QUT") and that the QUT would develop an appropriate course of training.

1. Ocular Therapeutic Endorsement and Legal Requirements

1.1 Ocular Therapeutic Endorsement

Optometrists must not administer, supply or prescribe registered restricted drugs unless they are endorsed by the Board to do so.

To apply for therapeutic endorsement, optometrists need to complete and submit to the Board an "Application for Ocular Therapeutic Endorsement" form which will be available at <http://www.optomboard.qld.gov.au>.

A register of Therapeutically Endorsed Optometrists ("the Register") will be kept by the Board and will be available on the Board website <http://www.optomboard.qld.gov.au/index.html>).

It is intended that the website of the Pharmacy Board of Queensland (<http://www.pharmacyboard.qld.gov.au>) will have a direct link to the Register and the list of Board approved registered restricted drugs.

Approved registrants will have a qualification on the register which reads "Therapeutically Endorsed."

1.2 Qualifications for Therapeutic Endorsement

In the interests of public safety, the Board must ensure that optometrists seeking therapeutic endorsement are suitably and appropriately qualified. The Board does not itself provide courses of study but approves courses offered by educational and professional bodies that, in the opinion of the Board, provide training which qualifies optometrists for endorsement of their registration. The Optometry Council of Australia and New Zealand ("TOC") or an equivalent body may conduct course assessments on the Board's behalf. National guidelines (the Optometry Council Guidelines on Accrediting Postgraduate Therapeutics Training) on the format of appropriate courses have been developed by TOC.

The aims of approved training courses are to permit endorsed optometrists to:

- (i) have in their possession, use or prescribe but not sell topical ocular registered restricted drugs as required for the practice of optometry;

- (ii) use those drugs appropriately for the treatment of ocular allergy, ocular infection, ocular inflammation, and toxic and traumatic conditions of the anterior eye.

The Board has currently approved QUT's course qualifying optometrists to a "Graduate Certificate in Ocular Therapeutics" and other courses may be approved in the future.

Therapeutically endorsed optometrists will be required to demonstrate their continued competency for endorsement. As part of the yearly optometric registration renewal process, therapeutically endorsed optometrists will be required to complete an additional section on the approved form where they will be asked to describe the steps they have undertaken in the past year to ensure their knowledge of ocular therapeutic issues remains current.

1.3 Registered Restricted Drugs Permitted to be Prescribed by Therapeutically Endorsed Optometrists

A therapeutically endorsed optometrist is permitted to be in possession of and to use, supply and prescribe only those registered restricted drugs specified in the Attachment. The list of drugs approved for use will be updated to ensure it maintains currency with accepted treatment standards and updated lists will be communicated to therapeutically endorsed optometrists (via Board mail-outs and the Board website) and to pharmacists (via the Pharmacists Board of Queensland's website). The amendments to the Regulation permit optometrists to issue prescriptions for ocular treatment only.

1.4 Supply of Registered Restricted Drugs by Endorsed Optometrists

The amended Regulation does not authorize optometrists to dispense registered restricted drugs under any circumstances. The term "supply" means to give, or offer to give, a person one or more treatment doses of a drug, to be administered by that person during a certain period. Optometrists may supply a registered restricted drug without charge but must not sell registered restricted drugs.

Optometrists can supply registered restricted drugs in the following circumstances:

- (i) in an emergency situation;
- (ii) in unusual clinical situations, in remote areas or after hours, or wherever access to a pharmacy is likely to be difficult; and
- (iii) as 'sample' or 'starter packs'.

1.5 Prescribing Registered Restricted Drugs by Endorsed Optometrists

Endorsed optometrists must take all reasonable steps to ensure a therapeutic need exists and prescribe/supply only for the ocular treatment of patients under their care. They must not write a prescription for use by anyone other than the patient named on the prescription. Prescriptions must comply with s 190 of the Regulation as summarized in the following paragraph.

Prescriptions must be handwritten (unless computer generated in a way authorized by the Regulation), signed by the optometrist and include the following information on the front of the prescription –

- the prescriber’s name, professional qualifications and address;
- the date it is written;
- the name and address of the person for whose use it is prescribed;
- the description of the restricted drug and the quantity or volume (in figures) of the drug;
- adequate directions about the use of the restricted drug;
- the dose to be taken or administered;
- a direction stating the number of times (after the first) the drug may be dispensed;
- if the prescriber is an optometrist – “For ocular treatment only”

The amendments to the Regulations do not allow optometrists to give verbal prescriptions to the pharmacist (all prescriptions must be written).

If a registered restricted drug is supplied, including samples, the pack must be labeled with the details specified in the s 198 of the Regulation. All endorsed optometrists will need to become familiar with this section and other requirements contained in the Regulation.

1.6 Storage of Registered Restricted Drugs

Storage of registered restricted drugs must comply with s 211 of the Regulation. For example, drugs must be kept in a cupboard, dispensary, drawer, storeroom or other part of the place to which the public does not have access.

1.7 Records of Use of Registered Restricted Drugs

Patient record cards must show the patient’s name and address, the date and the medication administered or supplied. Computer based records may be used.

Details of supply or administration of registered restricted drugs must be carefully recorded and retrievable for a period of three years. Records must show the name of the prescriber. Filing carbon copies of prescriptions would be sufficient to meet this requirement.

1.8 Complaints

Any complaints against an endorsed optometrist relating to diagnosis and management of ocular disease will be evaluated by the Board with reference to relevant legislation and the Protocol, other relevant documentation and professional opinion

The relevant legislation includes the *Optometrists Registration Act 2001*, *Health (Drugs and Poisons) Regulation 1996*, and the *Health Practitioners (Professional Standards) Act 1999* and can be found at <http://www.optomboard.qld.gov.au/links/links1.html>.

2. GENERAL GUIDELINES FOR THE USE OF REGISTERED RESTRICTED DRUGS

2.1 Expectations of Therapeutic Endorsed Optometrists

The Board expects a standard of best practice from endorsed optometrists in the diagnosis and management of eye disease. Practitioners should abide by their professional and ethical responsibilities as detailed in the Guide to Optometric Practice for Optometrists in Queensland available on the Board's website.

2.2 Knowledge and Skills

All optometrists who use and prescribe registered restricted drugs are expected to have a clear understanding of microbiological and pathological processes relevant to eye disease, typical presentations of eye disease, their differential diagnoses and identification of risk factors.

All optometrists using and prescribing registered restricted drugs are expected to have a sound knowledge of the pharmacology of these preparations, including:

- normal clinical response to their use;
- indications and contraindications to use;
- their potential side effects (topical and systemic);
- their interactions with other drugs; and
- how such complications can be avoided or managed.

Consulting room equipment should be commensurate with the ability to diagnose and monitor disease states. It is expected that optometrists would have access to equipment required for thorough assessment of anterior and posterior segments of the eye. The Board expects that endorsed optometrists will ensure their standard of care is appropriate. Their knowledge of relevant disease states and processes, together with the diagnosis and management of ocular disease, is expected to be current.

2.3 Clinical Assessment

Prior to initiating a patient on a course of registered restricted drugs, a thorough patient history must be taken to identify any factors that might predispose that individual to known side effects of drug use. This should be complemented by a thorough clinical examination to identify any factors that might contraindicate the use of such drugs.

2.4 Selection of Appropriate Registered Restricted Drug

Selection of an appropriate drug requires consideration of many factors, including:

- clinical history, signs and symptoms of condition;
- medical history (including current medications and known drug allergies);
- purpose of drug (prophylaxis vs. therapeutic);

- available preparations and their relative risk, benefit and efficacy;
- potential drug interactions; and
- alternative (non-pharmaceutical) treatments, and their relative benefits and efficacy.

Practitioners must ensure that they do not use registered restricted drugs unless clinically indicated.

2.5 Patient Information and Review

Optometrists commencing patients on a course of registered restricted drugs should:

- advise patients of the nature of the preparation, the recommended dosage and when their optometric review appointment is scheduled;
- perform regular reviews to monitor treatment efficacy;
- identify any side effects and/or complications as they develop;
- institute the necessary course of action to manage the patient's condition appropriately; and
- implement the plan after agreement with the patient.

2.6 Indications for Referral for Specialist Medical Treatment

Optometrists managing eye disease must be mindful of the potential complications of such conditions, have a clear understanding of when referral for specialist medical treatment is required and ensure, when such referral is indicated, that this occurs in a timely fashion.

2.7 Clinical Pathways

The purpose of the clinical pathways is to ensure high quality patient care and good clinical outcomes (Queensland Health Clinical Pathways Development Framework, Quality Improvement and Enhancement Program, 1999-2004). The pathways are an important quality assurance mechanism leading to safe practice by optometrists. They outline the range of ocular conditions and the roles of optometrists in the delivery of therapeutic eye care. They are evidence-based management plans which describe a sequence of interventions and clinically appropriate care, allowing always for the place of clinical judgement in that care. The Board will consider that endorsed optometrists have acted in accordance with the Protocol if they treat and/or manage a patient's ocular condition in line with the relevant clinical pathway, or in another way that is appropriate for the person's ocular care.

The clinical pathways have been developed by the QUT and will be revised in line with available prescription drugs and evolving standards of care. The clinical pathways are available on the Board's website and currently include:

Blepharitis

Hordeolum

Dry eye

Bacterial conjunctivitis

Viral conjunctivitis

Allergic conjunctivitis/keratoconjunctivitis
Bacterial keratitis
Viral keratitis
Herpes Zoster Ophthalmicus
Acanthamoeba keratitis
Fungal keratitis
Episcleritis

The current list of “Registered Restricted Drugs approved by the Board for Topical Use” forms an Attachment to this Protocol. The Clinical Pathways and the Guide to Optometric Practice for Optometrists in Queensland can be found at

<http://www.optomboard.qld.gov.au/>

ATTACHMENT

LIST OF APPROVED REGISTERED RESTRICTED DRUGS FOR TOPICAL USE AS AT 23 JUNE 2005

Topical ocular anti-infective agents (anti-bacterial, anti-viral)

Aciclovir
Bacitracin
Chloramphenicol
Ciprofloxacin
Framycetin
Gentamicin
Gramicidin
Neomycin
Ofloxacin
Polymixin
Tetracycline
Tobramycin

Topical ocular anti-allergy agents (anti-histamine, mast cell stabilisers)

Cromoglycate
Ketotifen
Levocabastine
Lodoxamide
Olopatadine

Topical non-steroidal anti-inflammatory agents (NSAIDs)

Diclofenac
Flurbiprofen
Ketorolac

Topical ocular steroid preparations

Fluorometholone
Hydrocortisone

Mydriatics, miotics and cycloplegics

Atropine
Cyclopentolate
Homatropine
Phenylephrine
Pilocarpine
Tropicamide

Local anaesthetics

Amethocaine
Oxybuprocaine
Proxymetacaine