Optometrists’ Formulary
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1. **MEDICINES LEGISLATION IN OPTOMETRIC PRACTICE (FROM 7 APRIL 2005)**

1.1. Under the Medicines Act 1968 medicines classified as Pharmacy (P) medicines may be sold or supplied only through registered pharmacies by or under the supervision of a pharmacist (section 52). Prescription only (POM) medicines are subject to an additional requirement: they may only be sold or supplied through pharmacies against a doctor's or dentist's prescription (section 58). General Sale List (GSL) medicines may be sold more widely through other retail outlets (sections 51 and 53).

1.2. Exemptions from the general rules are permitted for optometrists. These are provided for in the Prescription Only Medicine (Human Use Order) 1997 SI No 1830 (The "POM Order"), the Medicines (Pharmacy and General Sale- Exemption) Order 1980 SI No 1924 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 SI No 1923.

1.3. Provided **it is in the course of their professional practice**, registered optometrists may sell or supply the following medicinal products to a patient:

- All medicinal products on a General Sale List
- All P medicines

The emergency requirement has now been removed from the supply of GSL and P medicines.

1.4. The College will shortly be producing guidelines on supplying such products to patients and in the meantime it is recommended that patients only be supplied with these products following on from an eye examination, or if the optometrist is of the opinion that there is an indication for these products. In making such a supply optometrists should be aware of the cautions, contraindications and side effects of any medicinal products supplied.

1.5. **Provided it is in the course of their professional practice and in an emergency**, registered optometrists may sell or supply

- POMs which are not for parenteral administration and which
  
  a. are eye drops and contain not more than 0.5 per cent Chloramphenicol or
  b. are eye ointments and contain not more than 1 per cent Chloramphenicol
  c. contain the following substances:

  Cyclopentolate hydrochloride
  Fusidic Acid
  Tropicamide

The POMs to which this exemption applies may also be sold or supplied by a person lawfully conducting a retail pharmacy business on the presentation of an order signed by a registered ophthalmic optician.

1.6 Whether it is an emergency or not is at the discretion of the optometrist, but the criterion is whether the supply of the drug is an emergency, rather than whether the...
condition the patient has is an emergency. If the optometrist decides that the supply is not justified as being an emergency, s/he should give the patient a written order for the patient to obtain the drug from a pharmacy. Further information can be found in the Guidance for Professional Conduct 2.

1.7. An order made under the Opticians Act 1989 provides that where it appears to a registered optometrist that a person consulting him/her is suffering from an injury or disease of the eye, the optometrist shall refer that person to a registered medical practitioner, except in specified circumstances including an emergency or where otherwise it is impractical or inexpedient to do so or there is no justification for such a referral. There is no legal definition of what is “an emergency” for the purposes of the Medicines Act exemptions or the specific criteria governing referral requirements under the Opticians Act. It is therefore for the optometrist to make a professional judgement as to whether there is in fact an emergency and what measures need to be taken in the best interests of the patient, bearing in mind the Opticians Act, the GOC rules and Medicines legislation.

1.8. All POMs and P medicines to which Medicines Act exemptions apply may be sold to a registered optometrist by way of wholesale dealing.

1.9. In addition, under the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, a registered optometrist may obtain the following medicinal products by way of wholesale dealing:

P medicines for administration in the course of his professional practice.

POM medicines for administration (as opposed to sale or supply) containing the following substances:

- Amethocaine (tetracaine) hydrochloride
- Lignocaine (lidocaine) hydrochloride
- Oxybuprocaine hydrochloride (benoxinate)
- Proxymetacaine hydrochloride

Framycetin, which was previously available on an administration only basis, has now been removed from this list.

1.10. An order for POMs should include: optometrist's name and address, the date, name and address of the patient (if applicable), the purpose for which the POM is to be supplied (eg use in professional practice, refraction, etc), name, quantity, and except where apparent from the name, the pharmaceutical form and strength of the POM, labelling directions (where applicable), the signature of the optometrist (which must be original). The signed order must be written in indelible ink (includes typewritten and computer generated orders).

It should be noted that this list only contains substances most commonly used by optometrists.

2 www.college-optometrists.org Guidance for Professional Conduct, section 40, Use of Drugs in Optometric Practice
Notes on medicines legislation in optometric practice

1.11. The supply of 'exempted' POMs and ophthalmic Pharmacy Medicines from a pharmacy or pharmaceutical manufacturer to a registered optometrist (for use in his/her practice) is by way of wholesale dealing, whereas the sale or supply to his/her patient is a retail sale.

1.12. Legal requirements for wholesale dealing and retail sale for 'exempted' POMs from a pharmacy require that the optometrist's signed order be retained for two years from the date of the supply.

1.13. Such an order must include: optometrist's name and address; the date; name and address of the patient (if applicable); the purpose for which the POM is to be supplied (e.g. use in professional practice, refraction, etc.) name, quantity, and except where apparent from the name, the pharmaceutical form and strength of the POM; labelling directions (where applicable); the signature of the optometrist (which must be original). The 'signed order' must be written in indelible ink (includes typewritten and computer generated orders). The AOP have produced an example of a written order 3. More detail of what should be included in written orders used for therapeutic purposes will be issued by the College in the near future.

1.14. No pharmacy records need be kept of orders that are for Pharmacy Medicines or GSL medicines. In some cases no P medication is licensed in the United Kingdom and the formulation is only available as a POM. Therefore the container must be checked to see if it is labelled P before it may be used, sold or supplied.

1.15. The Medicines Act gives the Minister powers to control both contact lenses and their associated preparations.

1.16. Prior to January 1st 1995, contact lens care products received product licences from the Medicines Control Agency (now MHRA). Any contact lens product marketed after mid June 1998 must have the CE marking. It should be noted that if an optometrist wishes to re-label a contact lens care product i.e. ‘own branding,’ the MHRA has information for ‘own brand labelling.’

1.17. Finally it must be emphasised that these notes are an outline guide to some of the more important factors applicable to the legal use of ophthalmic drugs by the optometrist. They are not intended to cover all the legal requirements of the Medicines Act 1968 and its related Statutory Instruments with which s/he must comply.

Additional drugs available to optometrists who have undergone additional training

1.18. In addition to the drugs above, which can be accessed by all (‘Level 1’) optometrists, optometrists who have undertaken a course of further training approved by the GOC may apply for ‘Level 2’ exemption status. The competencies which need to be attained are on the websites of the GOC (www.optical.org) and National Prescribing Centre (www.npc.co.uk).

1.19. Atropine and pilocarpine, that were previously available to all optometrists, have now been transferred to the level 2 list. The level 2 list additionally includes: further antimicrobials, anti-histamines, mast cell stabilisers, a NSAID and a mycolytic drug.

**Contact for further information**
For further information please contact the Sale and Supply section, MHRA, 16-142, Market Towers, 1 Nine Elms Lane, London SW8 5NQ, telephone 020 7084 2392, fax 020 7084 2121 or e-mail info@mhra.gsi.gov.uk

2. **REPORTING SCHEMES ON ADVERSE REACTIONS**

The optometrist is able to report adverse reactions to drugs using the Yellow Card Scheme. The patient’s General Medical Practitioner should be informed of any suspected adverse reaction.

**Yellow Card Scheme – MHRA**

2.1 **Report:**
- Any suspected adverse reaction to ophthalmic medicines.
- Ocular adverse reactions to any therapeutic agent (drugs, herbal and homeopathic remedies, vaccines)

These medicines may be prescribed or purchased ‘over the counter’. Do not report on Medicines Devices (see later).

2.2 **Established Ophthalmic Medicines and Therapeutic Agents**
Optometrists are asked to report all suspected reactions.

2.2a. Adverse reactions to ophthalmic medicines.
- These include those that are fatal, life-threatening, disabling, incapacitating, or which result in or prolong hospitalisation; they should be reported even if the effect is well recognised. Examples include anaphylaxis, endocrine disturbances, haemorrhage from any site, ophthalmic disorders (see below), severe CNS effects, severe skin reactions, any drug interactions. Do not report well-known, relatively minor side effects, such as dry mouth with atropine eye drops.

2.2b Ocular adverse reactions to therapeutic agents
- These include any change in vision, any significant increase or decrease in intraocular pressure, any change in ocular structures e.g. lens, retina, cornea. It does not include allergies.

2.3 **Newer Drugs and Vaccines**
Optometrists are asked to report all suspected reactions.

2.3a. Newer drugs are indicated by the symbol ▼. An inverted black triangle against a product entry in the British National Formulary (BNF), MIMS (Monthly Index of Medical Specialists) or ABPI Compendium of Data Sheets and Summaries of Product Characteristics indicates that the Committee on the Safety of Medicines/MHRA are intensively monitoring that product.

2.3b. Adverse reactions to newer ophthalmic medicines.
Report any adverse or any unexpected event, however minor, which could conceivably be attributed to the drug. Reports should be made despite uncertainty about a causal relationship, irrespective of whether the reaction is well recognised, and even if other drugs have been given concurrently.

2.3c. Ocular adverse reactions to newer therapeutic agents. Report all ocular adverse reactions whether major or minor. These include ocular allergies.

2.4 Special Problems

2.4a. Delayed drug effects. Some reactions (e.g. chloroquine retinopathy) may become manifest months or years after exposure. Any suspicion of such an association should be reported.

2.4b. The elderly. Optometrists are asked to be particularly alert to adverse reactions in the elderly.

2.4c. Congenital abnormalities. When an infant is born with an ocular congenital abnormality, optometrists are asked to consider whether this might be an adverse reaction to a drug and to report all drugs (including self-medication) taken during pregnancy.

2.4d. Cards are obtained from and returned to MHRA. The Yellow Card Scheme was reviewed in 2004 and one of the recommendations was that patients should be able to submit reports. This recommendation was accepted and patients can now submit reports directly via www.yellowcard.gov.uk

Medical Devices Reporting Form – MHRA

2.5 Report any suspected adverse reaction to contact lenses, contact lens care products (solutions etc.), contact lens products (e.g. contact lens cases) and intraocular viscoelastic solutions. Optometrists are asked to report all serious suspected reactions: the following incidents are considered as “serious” and should therefore be reported.

2.5a Known ocular irritation, sensitisation or allergy

2.5b Known infection by the following organisms in the eye, the contact lens, the contact lens care product or the contact lens case.
   - any virus
   - any form of acanthamoeba
   - pseudomonas aeruginosa
   - staphylococcus aureus
   - escherichia coli
   - candida albicans
   - aspergillus niger
   - serratia marcesens
   - fusarium solani

2.5c If the contact lens or the contact lens care product has been recalled for technical reasons.

2.6 When submitting a report, optometrists are asked to include information about the contact lens material (the generic name will suffice) and the origin of the contact
lens care case. This latter is especially important where the case does not come from the solution manufacturer.

2.7. In addition to optometrists, contact lens opticians are well placed to observe suspected adverse reactions. Their participation in reporting these is encouraged.

2.8. Reports should be made to Adverse Incident Centre, MHRA (Devices), 2nd Floor Market Towers, 1 Nine Elms Lane, London SW8 5NQ Incident hotline 020 7084 3080 (www.mhra.gov.uk)

3. GENERAL INFORMATION

Preservatives
3.1 The preservative type and concentration of each of the products is listed as a percentage concentration. All concentrations for eye drops are expressed as a percentage weight in volume. For eye ointments and other solids, the concentration is expressed as a percentage weight in weight. All Minims® preparations are preservative free, but these, and other drops without preservative, often contain other excipients (e.g. buffers), and may still cause allergy or contact sensitivity.

Doses
3.2 The conjunctival sac can normally accommodate volumes of between 7µl and 30µl. Volumes in excess of this can be systemically absorbed which may give rise to adverse effects. It is therefore important to instil only one drop at a time.

3.3 In the case of multiple instillation, it is recommended to leave a minimum of 3 minutes between instilling drops. Where different drugs are used, the order in which different drops are instilled is not particularly important. Drops which sting should normally be used last as these cause reflex tear secretion which may reduce the effectiveness of subsequent instillations.

3.4 Eye ointments are applied by placing approximately 0.5cm ribbon of the ointment to the inside of the lower lid. Where ointments and drops are used together, ointments are instilled after drops.

Adverse reactions
3.5 It must be borne in mind that all drugs can cause contact sensitivity. Lanolin or lanolin derivatives are often used in eye ointments and may give rise to hypersensitivity reactions. In addition, there are few well-controlled studies concerning the use of drugs in pregnancy. Their use, especially during the first trimester, must be balanced against the risk to the foetus. Where no adverse reaction is stated, limited use by the optometrist is unlikely to produce significant adverse effects.

Storage
3.6 If no recommendations are given, store at or below 25°C.
4. ADDITIONAL SOURCES OF INFORMATION

4.1. British National Formulary (BNF)
Published every March and September by The Royal Pharmaceutical Society of Great Britain (RPSGB) and the British Medical Association.
Available from The Pharmaceutical Press, PO Box 151, Wallingford, Oxon OX10 8QU or any bookseller.
www.bnf.org.uk

4.2. MIMS (Monthly Index of Medical Specialities)
Published by Haymarket Medical Ltd.
Subscription enquiries: MIMS Subscriptions, Galleon Ltd., PO Box 219, Woking, Surrey GU21 1ZW.

4.3. ABPI Compendium of Data Sheets and Summaries of Product Characteristics
Published annually by Datapharm Publications Ltd, 12 Whitehall, London SW1A 2DY.
www.medicines.org.uk

4.4 Chemist and Druggist online directory
http://dir.dotpharmacy.com/

5. DRUGS AVAILABLE TO ALL OPTOMETRISTS

CYCLOPLEGICS AND MYDRIATICS (Antimuscarinics)
5.1 These drugs block the actions of the parasympathetic nervous system and are pharmacologically known as antimuscarinics, anticholinergics, cholinergic antagonists, muscarinic antagonists, parasympathetic antagonists or parasympatholytics. Their use in optometry is to relax the iris sphincter muscle and ciliary muscle, thus causing mydriasis and cycloplegia.

5.2 The above compounds may cause significant systemic adverse effects, mainly seen in children and the elderly, when used topically. These include: dry mouth, tachycardia (increased heart rate), dryness and flushing of skin, thirst, restlessness, irritability, disorientation and respiratory depression.

5.3 Cyclopentolate and tropicamide are synthetic compounds which have less potential for causing contact sensitivity than the alkaloids mentioned above. Both have a rapid onset of action and are short acting, mydriasis occurring in about 15 minutes. Cycloplegia takes longer. Effects can last for up to 24 hours with cyclopentolate, and approximately 4 to 6 hours with tropicamide. Mydriasis lasts longer than cycloplegia. Tropicamide is not a reliable drug for cycloplegic refraction in patients in their mid teens or younger.

5.4 Both drugs are used extensively by optometrists for examination purposes, though cyclopentolate and tropicamide do not cause complete cycloplegia. Following examination, mydriasis and cycloplegia are usually allowed to wear off naturally. Whilst the patient's acuity remains reduced, or there is a possibility of glare from the sun or car headlights as a result of pupillary dilatation, the patient should be advised not to drive or operate machinery. Should the patient develop an acute attack of closed angle glaucoma, they should be referred as per local protocols. The
antimuscarinic drugs should not be used on patients with narrow anterior chamber angles, or on those with Iris Clip intra-ocular lenses.

5.5 Adverse effects with cyclopentolate and tropicamide are not common although there have been significant isolated reports of altered mental state using cyclopentolate. Heavily pigmented eyes do not dilate readily, therefore care should be taken to prevent overdose.

5.6 Normal pupil reactions (or reflexes) to light and near vision are abolished by the antimuscarinic drugs.

MYDRIATICS AND DECONGESTANTS (Sympathomimetics)
5.7 Sympathomimetics or adrenoceptor agonists mimic the action of noradrenaline on the sympathetic nervous system. They are used in optometry and ophthalmology to cause mydriasis (e.g. phenylephrine), vasoconstriction (e.g. naphazoline), and lowering of intraocular pressure (e.g. adrenaline).

5.8 These drugs do not cause appreciable cycloplegia. Their systemic adverse effects reflect their actions on the sympathetic nervous system, resulting in palpitations, tachycardia, hypertension, and headaches. Patients taking systemic medications which have sympathomimetic activity may potentiate these adverse effects. Interaction with monoamine-oxidase inhibitors can cause a dangerous rise in blood pressure. Monoamine-oxidase inhibitors should be stopped for at least 2 weeks before the patient uses another drug with sympathomimetic actions.

LOCAL ANAESTHETICS
5.9 A number of different topical local anaesthetics have been developed over the years, but nearly all of them, when first applied, cause stinging and irritation. The toxicity of the drugs varies, the most toxic being amethocaine/tetracaine.

5.10 The local anaesthetics act by stabilising cell membranes, thus preventing nerve impulse transmission. The anaesthetics optometrists are able to use in their practice are lignocaine/lidocaine, amethocaine/tetracaine, oxybuprocaine/benoxinate and proxymetacaine. The duration of action is dependent upon dose, but they are generally effective for about 20 to 30 minutes. All local anaesthetics may cause corneal disturbances.

ANTIMICROBIALS
5.11 Antimicrobial agents may be used prophylactically or therapeutically for the treatment of minor eye infections.

5.12 Chloramphenicol is a useful antibiotic because it is effective against a wide range of Gram negative and Gram positive organisms, particularly Staphylococcus aureus which frequently causes ocular infections. As with all antibiotics a single instillation serves no useful purpose, repeated instillations are necessary whether for treatment or for prophylaxis. Thus when an optometrist uses chloramphenicol, arrangements must be made for continued instillation of the drug, until medical advice or treatment can be obtained, or in the professional opinion of the practitioner, the patient is no longer at risk.

ANTI ALLERGICS
5.13 Antazoline is an antihistamine and is used in the short term relief of allergic symptoms. It is available in combination with xylometazoline, which is a sympathomimetic and causes conjunctival vasoconstriction. Sodium cromoglycate/cromoglicate is believed to act by stabilising mast cells, thereby inhibiting the release of inflammatory mediators. Sodium cromoglycate/cromoglicate is available as a Pharmacy Medicine (P) and as a Prescription Only Medicine (POM). It is licensed as a (P) for the treatment of acute seasonal and perennial allergic (allergic) conjunctivitis.

ARTIFICIAL TEARS, LUBRICANTS AND IRRIGATIONS

Artificial Tears
5.14 Artificial tears consist mainly of non-medicated viscous solutions. There are some important differences between the various products.

pH
5.15 Optimum comfort seems to be achieved by drops that are slightly alkaline with pH in the region of 8.5.

Buffers
5.16 Buffers are used to regulate pH. Commonly used buffers in ophthalmic products are borates, acetates, bicarbonates and phosphates. Rarely, borate toxicity can occur.

Osmolarity
5.17 The normal osmolarity of tears is approximately 300 milliosmoles/kg. The osmolarity of artificial tear preparations is usually adjusted to this figure. Hypotonic agents have been shown to be beneficial in some instances.

Preservatives
5.18 Frequent use of artificial tears may cause preservative toxicity in about 9% of patients and consideration should be given to using preservative free solutions in patients showing signs of toxicity. The use of certain preservatives with soft contact lenses may be contraindicated, therefore the manufacturer's recommendations must be followed for individual products.

Acknowledgements

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Further information can be found at www.college-optometrists.org
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