Legislation and the optometrist

Professor John Lawrenson reviews the current law regarding sale and supply of drugs by optometrists in the UK

Although there have been controls on the use and supply of medicinal products in the UK dating back to the 19th century, it was not until the enactment of the Medicines Act in 1968 that the regulation of medicines was formalised. The Medicines Act and subsidiary statutory instruments currently provides the basic legislative framework for medicines control, although several European Directives which have been transposed into UK law, also regulate the licensing of medicines and medical devices.

UK optometrists were among the first optometrists in the world to legally use diagnostic drugs in the course of their professional practice and historically have used antibacterial agents for prophylaxis following scleral contact lens fitting, applanation tonometry and foreign body removal (Mitchell 1959). The Medicines Act has traditionally granted exemptions from the general rules laid down in the Act to allow optometrists to use certain prescription-only medicines (POMs) in the course of their professional practice and in particular circumstances to supply them to their patients. The last 10 years has seen radical changes in medicines legislation that has impacted on the optometric profession (Figure 1).

The most widely publicised change within this period was the introduction of optometrist independent prescribing. The concept of independent prescribing by non-medical health professions was first proposed in the Crown 'Review of Prescribing, Supply and Administration of Medicines', and following a change in June 2008, optometrists were given the opportunity to obtain the necessary accreditation to prescribe any licensed medicine for ocular conditions affecting the eye and surrounding tissues. Since 2000, there have been several other important legislative changes relating to the use and supply of medicines that have impacted on all registered optometrists. The purpose of this article is to review these changes and highlight their significance for clinical practice. The article will also summarise recent legislation regulating medical devices, which is relevant to the licensing of contact lens care products and artificial tear preparations.

Medicines legislation

Changes to the GOC rules relating to injury or disease of the eye in 2000, formally allowed optometrists to use their professional judgement to decide not to refer a patient with an ocular abnormality to a medical practitioner and to render appropriate therapeutic treatment. However, at this time, restrictions to the availability of pharmaceutical agents severely limited the ability of the optometrist to manage common non sight-threatening conditions. Two main legislative changes occurred in 2005 that went some way to removing these barriers (Titcomb and Lawrenson 2006):

- Update to the list of POMs available to all registered optometrists
- Removal of the 'emergency' requirement for the sale and supply of Pharmacy (P) and General Sales List (GSL) medicines.

Prior to 2005, the list of POMs available to optometrists had only been updated sporadically and was in urgent need of a major review. Moreover, several included drugs were no longer commercially available in the UK. In the case of antimicrobial preparations, chloramphenicol was the only POM available to optometrists for treating superficial infections of the eye or as prophylaxis following ocular surface injury. Although framycetin sulphate was listed, it was of little clinical value as its use was restricted to administration only. The 2005 changes consolidated the list of POMs available to optometrists and at the same time added the antibacterial agent fusidic acid to the POMs available for sale and supply (Table 1).

The POMs that are available to optometrists for supply can be sold or supplied directly to patients in emergency situations only. Routinely, these drugs should be supplied via an order written by the optometrist, which can be presented by the patient to a registered pharmacist (signed order). An order for POMs should include:

- The optometrist's name and address
- The date
- The name and address of the patient (if applicable)
- The name of the drug
- Quantity, pharmaceutical form and strength of the POM (eg 0.5 per cent eye drops 10ml)
- Labelling directions (where applicable)
- The original signature of the optometrist.

The signed order must be written in indelible ink; this includes typewritten and computer-generated orders. The College of Optometrists' guidance recommends that the optometrist's GOC number should also be included (College of Optometrists 2012).

The 2005 legislation also removed atropine sulphate and the miotic pilocarpine from the list of exemptions available to all optometrists. These drugs were transferred to the 'additional supply' list, which meant that further training and accreditation was required to use and supply these drugs.

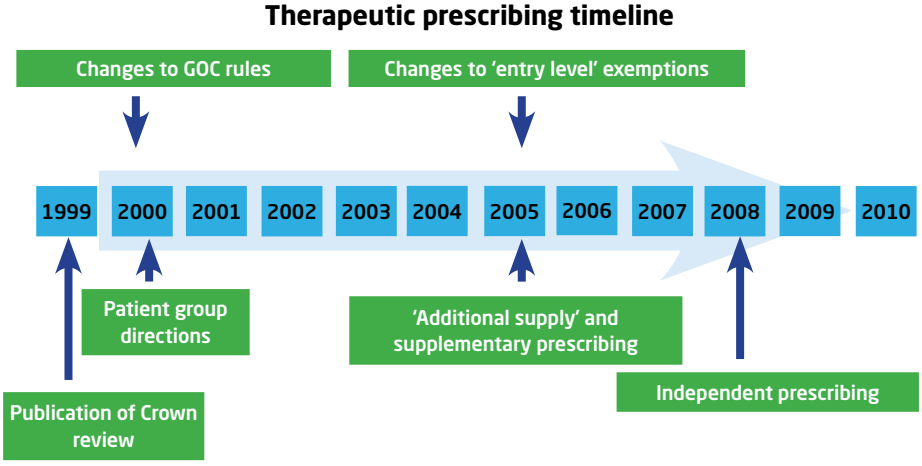

Figure 1 Changes to medicines and other relevant legislation relating to the use and supply of medicines and prescribing

TABLE 1

List of POMs available to all registered optometrists subsequent to the 2005 changes in legislation

Prescription-only medicines which may be sold or supplied by optometrists in the course of their professional practice and in an emergency. These drugs can also be routinely supplied via a signed order	Prescription-only medicines which optometrists may purchase for use in their practice. These may not be sold or supplied
Eye drops or eye ointments that are prescription-only medicines by reason only that they contain: eye drops containing not more than 0.5% chloramphenicol, or eye ointments containing not more than 1% chloramphenicol	Tetracaine (amethocaine) hydrochloride Lidocaine (lignocaine) hydrochloride Oxybuprocaine (benoxinate) hydrochloride Proxymetacaine hydrochloride
Fusidic acid Cyclopentolate hydrochloride Tropicamide	

TABLE 2

Examples of ophthalmic P medicines

Drug category	Drug	Products containing drug
Anti-histamine (topical)	Antazoline sulphate	*Otrivine Antistin*
Anti-histamine (oral)	Acrivastine Cetirizine Loratadine	*Benadryl Allergy Relief* *Zirtek Allergy Tablets* *Clarityn Allergy Tablets*
Mast cell stabiliser	Lodoxamide Sodium cromoglicate	*Alomide Allergy Eye Drops* *Opticrom Allergy Eye Drops*
Antimicrobials	Chloramphenicol* Propamidine	*Optrex Infected Eye Drops* *Brolene*
Ocular lubricant	Liquid paraffin	*Lacri-lube Ophthalmic Ointment*
Stains	Fluorescein Rose bengal	Fluorets Rose Bengal Ophthalmic Strips
Sympathomimetic	Phenylephrine	*Minims Phenylephrine*

*for acute bacterial conjunctivitis only

Another important legislative change in 2005 was a relaxation of the law governing the supply of P and GSL medicines by optometrists. It was recognised that the restriction on supply of these agents to 'in an emergency' was unnecessarily restrictive. The removal of the emergency restriction allows the direct supply to patients of any P medicine that is used in the course of an optometrist's professional practice eg lubricants, anti-allergy preparations and antimicrobials (Table 2).

The College of Optometrists has produced detailed guidance regarding the use and supply of P Medicines in optometric practice, which is available from the College website. Although legally the drugs can be sold from optometry practices, the College Guidance states:

If they are supplying therapeutic drugs to their patients, practitioners have a duty to ensure that this drug is appropriate for the patient. This will mean the optometrist has to make a diagnosis of the patient's condition. Supply should normally only be made following an eye examination, or within a reasonable time afterwards. Patients should be made aware of the need to have their condition periodically reassessed to determine whether or not the drug is still appropriate. This is particularly important if the patient has already sought treatment elsewhere. All actions and advice should be noted on the patient record.

Another mechanism by which optometrists can supply medicines is through Patient Group Directions (PGDs) (MHRA 2012). PGDs are 'written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'. PGDs have been used widely by optometrists in the Hospital Eye Service eg in the accident & emergency department and glaucoma clinics (Steele 2005). The legislation, which also applies in community optometry practice, specifies that each PGD contains specific information including:

- A description of the medicine(s) to which the direction applies (including dose, route of administration and duration)
- Description of the condition for which the direction applies.

PGDs should be drawn up by a multi-disciplinary team, including a doctor, a pharmacist and a member of the professional group expected to supply the medicine. Furthermore, arrangements need to be put in place for the security, storage and labelling of each medicine included on the PGD.

Medical device legislation

The term 'Medical Device' encompasses a vast array of products ranging from intra-ocular lenses to dialysis equipment and eye-baths to corn plasters. In general, a medical device cannot be licensed within Europe without carrying a CE mark. The CE mark guarantees that the device meets the relevant regulatory standards, works as intended and is acceptably safe. Usually the distinction between a medical device and a medicine is fairly clear cut, however when it comes to ophthalmic products the classification can sometimes be confusing. Historically, the legislation on medicinal products predated medical device regulation (MDR) and so when regulation of medical devices came into force, some products transferred their regulatory control to MDR eg contact lens care products. More recently, as a result of changes to the definition of a medicinal product in European Directive 2004/27/EC, other categories previously regulated as medicines are now considered to be medical devices eg artificial tears. However, since each application is assessed on a case by case basis there are some apparent anomalies.

Although the action of a medicinal product is typically achieved by pharmacological means, a substance administered for diagnostic purposes, even though it doesn't act in this way, is also considered to be a medicinal product rather than a medical device. This explains why diagnostic stains eg fluorescein paper strips and rose bengal are classed as P medicines and are therefore regulated by the Medicines Act. This was clarified in a recent bulletin from the Medicines and Healthcare Products Regulatory Agency (MHRA 2011). The discontinuation of rose bengal in minims has promoted the increased use of lissamine green as an alternative. Although lissamine green can be imported into the UK or purchased online it does not have a UK licence. However, should an application be made, its similarity to the other staining agents would suggest that it will also classified as a P medicine.

A further reading list is available from william.harvey@rbi.co.uk

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