

Factsheet: who can administer eyedrops?

Version 6.0, January 2007

What is mydriasis?

Mydriasis is the dilatation of the pupil to facilitate retinal photography. To improve the quality of captured images, a mydriatic agent such as guttae tropicamide 0.5% or 1.0% is usually applied prior to retinal photography. In some cases guttae phenylephrine 2.5% may also be required.

1. Safe systems of work

It is important, whatever the model of delivery, that safe systems of work are in place governing the administration of eye drops. Clear, written processes and protocols in relation to this, which should include detailed information about contra-indications and adverse reactions, should be maintained within the screening programme in a place easily accessed by the screeners. These should form the basis of training of staff who should also undertake the relevant modules in the National Certificate.

Access to medical advice in an emergency is also a consideration. Care should be taken to ensure that people presenting for screening are aware, prior to the appointment, of risks with regard to eye drops, actions they should take in the event of problems, and the fact that it will not be safe to drive for at least four hours after the appointment. The programme manager should ensure that the information that is sent to patients with the letter of invitation adequately covers these facts, and screeners should ensure that those attending to be screened have understood that information.

2. The Medical and Healthcare products Regulatory Authority (MHRA) advises as follows:

a) Is tropicamide 0.5% and 1.0% a Prescription Only Medicine (POM)?

Yes. However the medicines legislation regulates the requirement for a prescription in different ways depending on whether the eyedrops are being sold, supplied, administered parenterally (by injection) or externally.

b) Is phenylephrine 2.5% a POM as well?

No. Phenylephrine 2.5% is a Pharmacy (P) medicine. P medicines may be obtained by anyone for administration in the course of a business provided they are to be used within their licensed indications.

c) Does that mean that screeners can only administer eye drops if there is a prescription or other order such as a Patient Group Direction (PGD) or Patient Specific Direction (PSD)?

Not necessarily. The MHRA says that medicines legislation places no legal restriction on who can administer/instil eye drops such as tropicamide 0.5% and 1.0% and phenylephrine 2.5%, for the purposes of dilating the pupil for screening. This advice, however, is limited to **administration** only and not to the sale or supply of tropicamide. It is the wholesale acquisition, sale and supply of these eye drops that is restricted by the legislation and this might affect which organisations and individuals can legally acquire eye drops.

d) So who can legally acquire eyedrops?

The wholesale supply of medicine is regulated by medicines legislation. Generally, the wholesale supply of POMs is restricted to specified classes of person such as NHS Trusts, doctors and pharmacists. Some registered health professionals may also obtain certain POMs on a wholesale basis. This includes the wholesale supply of tropicamide to optometrists (but does not extend to dispensing opticians).

e) So how does that affect screening programmes in practice?

The following paragraphs are intended to provide information about the legalities of common scenarios involving the use of eye drops in retinal screening programmes. They are not definitive and while the MHRA is happy to offer further clarification where necessary, organisations should also be prepared to obtain their own legal advice.

(i) NHS Organisations

Retinal screeners employed by NHS bodies such as hospitals and Primary Care Trusts can access eye drops obtained by those bodies for administration in the course of their business. No prescription, PGD, PSD or other order is required. It is possible that agency staff operating within a Trust and under close supervision, and covered by the trust's insurance may be in a similar position but the MHRA suggest that individual trusts that intend to rely on this take advice from the trust's lawyer before doing so.

NHS bodies entering into an arrangement with an independent provider (or anyone else who is not part of their organisation) to provide screening services should be aware that unless they have a wholesale dealer's licence, they cannot legally supply stocks of POM and P medicines to that provider.

(ii) Optometrists' Practices

An optometrist may lawfully obtain stocks of tropicamide as well as P medicines for administration in the course of his/her business. Within the practice, the optometrist could allow employees to access these medicines for administration only, for example, in retinal screening procedures. There may be a question as to whether this is appropriate in terms of the optometrist's professional practice but this will be a matter for the professional body, the College of Optometrists, the current advice being: "If the optometrist themselves is not instilling the drop to the patient, the optometrist should be on the premises whilst this is being done so that they can intervene if necessary".

Further advice can be reviewed on the College of Optometrist website at:

http://www.college-optometrists.org/coo/download.cfm?uuid=E040B4CB-E554-80C1-9D8414ABF25FAD9B&type=ethics_guidelines

(iii) Independent Companies providing screening and grading services

Trusts using independent sector providers, such as companies providing screening and grading services, who employ registered health professionals (such as nurses) to administer eyedrops could enter into an arrangement to do this under a Patient Group Direction (PGD). The PGD would need to be authorised by the Trust concerned. In these circumstances, the company can obtain wholesale supplies of the medicines to be administered under the PGD. It should be noted that not all retinal screeners are registered healthcare professionals and the National Certificate alone will not result in that status.

There are no other specific provisions in medicines legislation for independent companies providing screening and grading services who are not registered with the Healthcare Commission to obtain wholesale supplies of POMs. However, an optometrist who is employed by an independent company is entitled to order and receive wholesale supplies of tropicamide. Legal advice obtained by the MHRA indicates that these supplies can be distributed to screeners

employed within the same company. Again, whether this is appropriate or not in terms of the optometrist's professional practice is a matter for the College of Optometrists. It may be prudent for optometrists to seek specific advice from the College of Optometrists when the company is supporting more than one programme, particularly those geographically dispersed where close supervision is problematical, the current advice being: "If the optometrist themselves is not instilling the drop to the patient, the optometrist should be on the premises whilst this is being done so that they can intervene if necessary".

This advice has been scrutinised and agreed by the MHRA, the body that is responsible for medicines legislation. This will be updated from time to time as the MHRA has the opportunity to consider individual cases. You can also see the advice on the MHRA website at:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=731

Legal references

Schedule 1 of The Prescription Only Medicines (Human Use) Order 1997 No 1830 lists tropicamide as a Prescription Only Medicine (POM).

S.58(2)(b) of the Medicines Act 1968 provides that no person shall administer a POM unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. (The Act identifies doctors, dentists and vets as appropriate practitioners, but subsequent statutory instruments extend the classes of people who fall within that group).

However Article 9 of the 1997 Order No 1830 says that 'the restriction imposed by section 58(2) (b) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration'.

As tropicamide is not administered parenterally it therefore means that the restrictions imposed by S 58(2)(b) do not apply to the administration of eye drops.

However it should be noted that S.58(2)(a) still applies to tropicamide so prescriptions or written orders are still required where there is to be sale by retail, or supply in circumstances corresponding to retail sale of tropicamide.

In addition the Medicines Act 1968 requires wholesale suppliers and manufacturers of tropicamide to be licensed and S.61 of the Act restricts the classes of people who can be supplied with POMs.

The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 SI No1980/1923 as amended lists the classes of person who can be supplied with POMs. This includes NHS bodies such as hospitals and Primary Care Trusts, doctors and pharmacists. Further information regarding other bodies can be obtained from the MHRA.

It has been suggested that Article 12 of the Prescription Only Medicines (Human Use) Amendment Order 2000 applies to the administration of eye drops as it refers to S58 of the Medicines Act. It should be remembered that the 1997 Order No 1830 removed the restrictions imposed by S58(2)(b) to POMs that are administered non-parenterally. Article 12 therefore does not apply to the external administration of eye drops although, of course, it still applies to the sale of tropicamide by retail or its supply in circumstances corresponding to retail or exposing it for sale by retail in certain circumstances. It would also still apply to all POMS that are administered parenterally.

This advice has been scrutinised and agreed by the MHRA, the body that is responsible for medicines legislation. It will be updated from time to time as the MHRA has the opportunity to consider individual cases.

Comments on this document should be sent to:

Fionna O'Leary, Programme Manager

fionna.o'leary@glos.nhs.uk