

Position statement on the use of fluorescein ophthalmic strips

1. The General Optical Council (GOC) has a statutory function to protect, promote and maintain the health and safety of members of the public. This includes protecting patients and promoting safe clinical practice through setting and upholding high standards of conduct. This document sets out the GOC's present view concerning the use of CE-marked fluorescein ophthalmic strips. It is being issued to assist registrants in ensuring they act in the interests of the public.
2. The use of fluorescein is an essential part of many practitioners' delivery of clinical care. We know that many registrants previously used Fluorets, which were the only form of fluorescein ophthalmic strips with a marketing authorisation (licence) as a medicine in the UK. These registrants are concerned about their ability to deliver care following the withdrawal of Fluorets from the market earlier this year. Following the withdrawal of Fluorets, we have stated that optometrists and contact lens opticians can safely and legally use fluorescein Minims (unit dose eye drops) as this product is licensed for use in the UK.¹ However, we have received a number of enquiries about whether practitioners can use CE-marked fluorescein strips as an alternative.
3. We have been working to obtain information on the legal and patient safety implications of our registrants using fluorescein strips that do not have marketing authorisation as medicines.

¹ http://www.optical.org/en/news_publications/news_item.cfm/update-on-fluorescein
(statement issued 24 May 2013)
http://www.optical.org/en/news_publications/news_item.cfm/goc-statement-on-fluorets
(statement issued 21 March 2013)

4. We are aware that a clinical consensus panel of experienced practitioners and academics has recently discussed and reported on the use of fluorescein ophthalmic strips by optometrists and contact lens opticians in UK primary care. We respect the clinical expertise behind the panel's view that:
 - 4.1 the failure to use fluorescein when clinically indicated in a primary care setting due to the non-availability of a suitable pharmaceutical preparation will put patients at risk;
 - 4.2 there are no specific safety concerns over the fluorescein strips currently available in the UK that have been CE-marked as a medical device in another EU state; and
 - 4.3 in certain clinical situations, it would be appropriate and more suitable to use CE-marked fluorescein strips as an alternative to the currently available unit dose eye drops.
5. We are aware that the Medicines and Healthcare products Regulatory Agency (MHRA) has decided not to take enforcement action in relation to the marketing and supply in the UK of fluorescein strips CE-marked in other EU states, pending a decision by the European Commission on the categorisation of fluorescein and such strips. The MHRA is an executive agency of the Department of Health, with responsibility for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe
6. We have received the following legal advice:
 - 6.1 UK optometrists and contact lens opticians may administer fluorescein within the scope of their clinical practice.
 - 6.2 In the UK, fluorescein ophthalmic strips are medicines (medicinal products), not medical devices.

- 6.3 However, on the basis that fluorescein ophthalmic strips have the benefit of a CE mark as a medical device in an EU member state, EU legislation prevents the imposition in the UK of obstacles to the sale and supply of such medical devices.
 - 6.4 The UK has not used its powers to block the supply of such CE-marked strips, on the contrary (as noted above) the MHRA does not presently object to the continuing supply.
 - 6.5 There is no specific criminal offence under the UK legislation of using a fluorescein product, CE-marked as a medical device, but not authorised as a medicine.
7. Each registrant is individually responsible for acting at all times in the best interests of his or her patients. Registrants must determine the most appropriate clinical care for each patient, acting in accordance with the GOC Code of Conduct including the requirements to:
 - 7.1 Make the care of the patient their first and continuing concern (part 1 of the Code for individual registrants)
 - 7.2 Give patients information in a way they can understand and make them aware of the options available; on the issue of patient consent, be aware of and comply with the guidance published by the professional bodies (part 5)
 - 7.3 Keep professional knowledge and skills up to date (part 8)
 - 7.4 Recognise, and act within, the limits of their professional competence (part 9)
 - 7.5 Be covered by adequate and appropriate insurance for practice in the United Kingdom throughout the period of their registration (part 18)

8. In the light of our legal advice, the stance of the MHRA and the unanimous opinion of the clinical consensus panel, we recognise that there will be circumstances where acting in patients' best interests requires an optometrist or contact lens optician to use CE-marked fluorescein strips. As noted by the panel, not using fluorescein when required is unacceptable and could delay detection of clinical problems that may result in sight loss.
9. Under the processes set out in the Opticians Act 1989 and the General Optical Council (Fitness To Practise) Rules 2005, we must refer all fitness to practise concerns to an independent body, the Investigation Committee, for a decision on whether the complaint is serious enough to be considered by another independent body, the Fitness to Practise Committee. We cannot prejudge these committees' decisions in any specific case.
10. However, we can assure registrants that we will ensure that the committees receive all relevant information, including:
 - 10.1 the views of the clinical consensus panel;
 - 10.2 the views of the MHRA; and
 - 10.3 our view that acting in patients' best interests, as required by the Code of Conduct, may make it necessary for registrants to use CE-marked strips (the marketing and supply of which is not currently opposed by MHRA), where they are acting within their scope of practice.
11. We will review this statement in the light of any significant further developments.

Note:

The GOC is the regulator for the optical professions in the UK. Its purpose is to protect the public by promoting high standards of education, performance and conduct amongst opticians. The Council currently registers around

26,000 optometrists, dispensing opticians, student opticians and optical businesses.