General Optical Council

Position statement on the use of lissamine green

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 view concerning the use of CE-marked lissamine green ophthalmic strips. It is being issued to assist registrants in ensuring they act in the interests of the public.

2. We understand that many registrants use lissamine green when assessing the ocular surface and that it is available as a CE-marked product for use as a 'diagnostic agent when superficial corneal or conjunctival change is suspected'. It is used regularly in the UK, particularly in the assessment of changes associated with dry eye disease.

3. We also understand that at least one company manufacturing lissamine green has CE-marked their product in the European Union (EU) as a medical device, but the Medicines and Healthcare products Regulatory Agency (MHRA) considers that it is an *in vivo* diagnostic product and therefore should be regulated as a medicinal product. Lissamine green does not currently have a marketing authorisation in the UK as a medicinal product.

4. The MHRA accepts that there may be instances where companies may supply lissamine green ophthalmic strips that have been CE-marked in EU member states, and has said that at the present time, no regulatory action will be taken against strips that are CE-marked as medical devices. They have informed us that this position applies pending a final decision on the correct regulatory route to be applied to products such

as fluorescein and lissamine green when used by optometrists and contact lens opticians.

5. We have been asked by professional bodies in the optical sector to clarify the position in relation to lissamine green. We advised them to form a clinical consensus panel of experienced practitioners and academics to discuss and report on the use of lissamine green by optometrists and contact lens opticians in UK primary care. We respect the clinical expertise behind the panel's view (which met on 24 April 2018) and their subsequent consensus statement that:

    5.1 lissamine green is a safe and valuable tool for the assessment of the ocular surface and its use by optometrists and contact lens opticians should be encouraged;

    5.2 no adverse incident relating to the use of lissamine green in a clinical practice setting had been reported to the knowledge of those involved in the consensus panel; and

    5.3 providing that the product being used is CE-marked the current lack of licensing in the UK should not prevent optometrists and contact lens opticians from using lissamine green in clinical practice.

6. The panel concluded: *"It is the view of the Clinical Consensus Panel based on the evidence available and practice and clinical opinion, that lissamine green is clinically safe to use and that optometrists and contact lens opticians in the UK may within their scope of practice use a CE marked lissamine green impregnated ophthalmic strip for clinical investigations of the ocular surface until further notice."*

7. Registrants are individually responsible for acting at all times in the best interests of their patients, and must determine the most appropriate clinical care in accordance with the GOC's *Standards of Practice for Optometrists and Dispensing Opticians*. These include requirements to:

7.1 listen to patients and ensure they are at the heart of the decisions made about their care (standard 1);

7.2 communicate effectively with patients, giving them information in a way they can understand (standard 2);

7.3 obtain valid patient consent and be aware of legal obligations in relation to consent (standard 3);

7.4 keep professional knowledge and skills up to date (standard 5);

7.5 recognise and work within the limits of their competence (standard 6); and

7.6 ensure a safe environment for patients and have adequate professional indemnity insurance (standard 12).

8. In the light of the stance of the MHRA and the unanimous opinion of the clinical consensus panel, we consider that there will be circumstances where it is necessary, in the patient's best interests, for optometrists and contact lens opticians to use CE-marked lissamine green ophthalmic strips (the marketing and supply of which is not currently opposed by the MHRA) within the scope of their practice.

9. We will review this statement in the light of any significant developments, including any revision to the MHRA's position.

Notes:

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 GOC currently registers around 30,000 optometrists, dispensing opticians, student opticians and optical businesses.

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.

The UK has left the EU and is in a transition period from 1 February to 31 December 2020. The UK will continue to stay aligned to EU law during the transition period. This statement will not be affected by the end of the transition period.