

Press Release

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OPTICAL CONFEDERATION PUBLISHES CLINICAL CONSENSUS PANEL ADVICE ON USE OF FLUORESCEIN STRIPS AND SUPPORTS THEIR USE IN ROUTINE COMMUNITY PRACTICE PENDING FURTHER ADVICE FROM EUROPE

The advice from the Clinical Consensus Panel is that the use of paper impregnated fluorescein strips, CE marked as medical devices, poses minimal risk and they may be used for clinical investigations in primary care until further notice.

Background to Clinical Consensus Panel Report

Since the announcement in March that Bausch & Lomb had discontinued the production of Fluorets, the only fluorescein impregnated paper strip licensed as a medicine in the UK, the Optical Confederation (OC), the British Contact Lens Association, the College of Optometrists and the General Optical Council have been considering how best to advise optical practices, optometrists and contact lens opticians in what has turned out to be a highly complex and unclear legislative and regulatory area.

Fluorescein strips have long been considered as borderline products and regulated as medicines in the UK, whereas they are regulated as medical devices in most of the rest of the EU. European non-binding guidance from MEDDEV issued in 2001 recommended their classification as medicines; however this depends on their precise use. Notwithstanding this recommendation, several European national authorities continue to consider the strips to be medical devices. The European Commission is aware of the difference of opinion regarding the classification of fluorescein strips and the issue is being considered in further detail by the relevant European authorities this autumn. In the meantime the MHRA has permitted the supply of CE marked medical device fluorescein strips to the UK market.

While the UK optical bodies worked to establish the expert opinion on whether use of these strips could be justified from a clinical perspective, we issued advice in May to use 1% fluorescein minims while these problems were resolved.

In the last couple of weeks another problem materialised. It was announced on 13 September that, despite Bausch & Lomb's best efforts, supplies of 1% fluorescein minims had also run out and would not be resumed until later this autumn.

Clearly patient care, safety and outcomes must be the top priority. While these issues are resolved at European level, in order to obtain the best clinical advice on both the safety and efficacy of alternative fluorescein products, the OC convened a panel of leading independent academics and clinicians to provide a consensus view on these issues at the end of July. Their unanimous, independent professional advice is attached. The report is available on the Optical Confederation website.

The advice from the Clinical Consensus Panel is that the use of paper impregnated fluorescein strips, CE marked as medical devices, poses minimal risk and they may be used for clinical investigations in primary care until further notice.

Statement by the Optical Confederation

On the basis of this clear, unambiguous and unanimous opinion the Optical Confederation advises that CE marked fluorescein impregnated strips can be used based on clinical judgement in the case of each patient in routine community optical practice. When ordering fluorescein strips, practices and practitioners should check that they are CE marked and permitted for sale in the UK. The Optical Confederation insurance bodies – the ABDO, AOP and FODO – will continue to cover and defend members, who use CE-marked fluorescein strips in the best interests of patients, in the normal way.

Practices and practitioners are advised to contact their Optical Confederation membership body if they have any questions.

Speaking for the Optical Confederation Mark Nevin said: “Patient care, safety and outcomes must always be our first and overriding concern in line with our Codes of Conduct. The Optical Confederation exists to support and assist members in delivering these goals for the public. Given the shortage of fluorescein minims, we are now faced with having to advise optometrists and contact lens opticians about whether they should perform, for example, a slit-lamp examination without fluorescein, rather than use a CE-marked product. Hence our advice to practices and clinicians to use CE marked strips to ensure patients continue to receive the best care. We also urge the European Commission to move quickly in patients’ best interests to resolve these unintended consequences of their guidance”.

Notes for editors

1. The Optical Confederation is a coalition of the five optical representative bodies: the Association of British Dispensing Opticians (ABDO); the Association of Contact Lens Manufacturers (ACLM); the Association of Optometrists (AOP); the Federation of Manufacturing Opticians (FMO) and the Federation of Opticians (FODO). As a Confederation, we work with others to improve eye health for the public good.
2. For further information on MEDDEV and the European regulatory framework, or basis for the clinical advice, please refer to the Clinical Consensus Panel which is available on the Optical Confederation website <http://www.opticalconfederation.org.uk/downloads/report-on-clinical-consensus-panel-on-the-use-of-fluorescein-in-primary-care-with-table-of-contents.pdf>
3. MHRA has decided not to take enforcement action against suppliers of CE marked medical device fluorescein strips to the UK market until the position in the EU has been clarified, therefore permitting their sale in the UK.