Fluorescein update – February 2015

Key points

- Current advice on the use of CE-marked fluorescein strips in community optical practice remains unchanged
- Much delayed discussions about the classification of fluorescein strips in the EU are about to restart but no significant progress is likely before the summer
- There are currently no problems with availability – and some new CE marked products have come onto the market
- No adverse incidents arising from the use of fluorescein strips have been reported in either Europe or the USA
- The Optical Confederation is a member of the European Council of Optics and Optometry (ECOO) which has submitted evidence and is tracking developments closely

Background

Fluorescein strips have been manufactured and supplied as CE marked medical devices across much of Europe since their introduction and are regularly and safely used by eye health professionals.

However the definition of "diagnosis" developed by the Borderline and Classification Expert Group's taskforce has caused fluorescein strips to be classified as a medicinal product, rather than a medical device. This requires a higher level of regulatory approval which risks making the supply non cost-effective for many suppliers.

ECOO has been working to have this definition and therefore the classification reassessed. In April 2014 Member States and a number of stakeholders, including ECOO and the Clinical Consensus Panel on fluorescein submitted evidence to the taskforce challenging the definition. The taskforce was then meant to review the definition. However no progress has been made and the meeting of the Expert Group planned for October 2014 was postponed to February 2015.

Where we are now

Our understanding is that the EU Expert Group will resume work this month and that a second round of discussions about the definition will take place. A pilot exercise is then planned to assess the impact the proposed classifications may have on the supply of several products, including fluorescein strips. The next meeting of the Expert Group that may address this issue is provisionally scheduled for 2 June 2015.

Next steps

The Optical Confederation, as part of ECOO, will continue to closely monitor progress and will seek to be involved in the new discussions on the definition and in the pilot project for fluorescein strips. We will continue to provide periodic progress reports to members.

ECOO asks member countries to report twice a year on any adverse incidents arising from the use of CE-marked fluorescein strips and monitors any adverse incidents reported to the FDA in the United States where use is even more widespread. To date no adverse events have been reported or noted. This evidence is used in discussions with the EU Expert Group.

Availability of fluorescein

There was initially a supply issue when fluorescein strips were classified as medicinal products. However suitable CE marked products have remained available and new products have also come onto the market. Practitioners should continue to use such strips in line with the guidance issued by the Optical Confederation Clinical Consensus Panel until further notice.

Further information

For further information about the work of the Optical Confederation and ECOO on fluorescein, contact Ann Blackmore at ann@fodo.com or 020 7298 5156

For queries about use of CE-marked fluorescein strips contact:

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