European Council of Optometry and Optics
Conseil Européen de l'Optométrie et de l'Optique
Europäischer Rat für Optometrie und Optik

PRESS RELEASE

ECOO urges EU Member States and the European Commission that Fluorescein is safe for use in community eye care and should be classified as a medical device

June 2012

Fluorescein strips, used in contact lenses fitting and to assess ocular health, have been considered and used as medical devices since their invention. Recently, confusion about its classification has caused significant supply problems in Europe. Non-binding guidance from Meddev suggests fluorescein strips be classified as medicinal devices, which greatly affects their manufacture and use in community eye care.

Fluorescein strips are a key tool when fitting contact lenses and to assess the integrity of the anterior segment of the eye. It is furthermore used in Goldmann applanation tonometry to assess intra-ocular pressure. In sum, about 5 million strips are safely used each year in Europe for these purposes and as such they are an integral part of an eye examination and of the work of eye care professionals when fitting contact lenses.

In terms of its classification, fluorescein has been considered a borderline case. This means that it does not easily fit into the definitions of the medical devices and the medicinal products directives. Despite this, fluorescein strips have routinely been used by eye care professionals across Europe since 1960 and have been widely considered as medical devices ever since.

Whilst the non-binding Meddev guidance document[1] drawn-up in 2001 classifies "fluorescent ophthalmic strips for diagnostic purposes" as medicinal products, it is only recently, that this has become a major issue. In 2011 the Swiss competent authority Meddec decided to follow this non-binding guidance, which has led to significant confusion there, in other countries and among manufacturers, some of which have now ceased production. The reasoning for this decision or the classification in the non-binding guidance, remains unclear and do not actually reflect the reality of the product's use or risk.

Armin Duddek, President of ECOO said "We have recently met with the European Commission to set out the practical difficulties that reclassification of fluorescein strips causes for our sector. We were reassured that this was not the intended consequence and that our views would be put to the Expert Group in October 2012. In the meantime the advice from ECOO is that practitioners can and should continue to use fluorescein to assess their patients in accordance with applicable national legislation."

Helmer Schweizer, President of Euromcontact said "Classification of fluorescein strips as medicinal products is an unnecessary restriction that adds significantly to the cost of production and approval before placing them on the market. While we fully favour appropriate regulation of medical devices, we

[1] Meddev Guidance Document: "Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative", http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

are not aware of evidence to restrict their use by optometrists and opticians in the community."

ECOO is in close contact with the European Commission to re-assess this situation. The "Borderline and Classification Medical Devices Expert Group" will meet in October 2012 to clarify the matter.

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