EU-EYE position

Classification of fluorescein paper strips as medicinal product to safeguard patient safety

EU-EYE, the European Alliance for Vision Research and Ophthalmology, comprises 9 European organisations[i] representing over 15,000 medical doctors specialised in the treatment of eye diseases and research. As the leading alliance of medical specialists' organisations in this area, EU-EYE calls on the relevant authorities and experts to classify fluorescein paper strips as a medicinal product. You can find our position detailed below. EU-EYE would also welcome any opportunity to provide you with more information and exchange views.

Fluorescein paper strips are mostly used for the diagnosis of ocular pathologies such as post-traumatic corneal erosions and dry eye diseases. In line with the MEDDEV guidelines[1] it therefore qualifies as a medicinal product and should subsequently be classified as such within the EU.

- The use of fluorescein for the assessment of tear break-up time for the diagnosis of dry eye diseases and for the diagnosis and treatment of post-traumatic corneal erosions is part of the work-up necessarily performed by or under the supervision of an ophthalmologist
- Fluorescein, even dispensed as an impregnated paper strip, can produce allergy and penetrate the anterior chamber of the eye whenever the integrity of the cornea is affected, as is the case in dry eyes or contact lens fitting
- The classification of fluorescein as medical device could incur risks to patient safety
- Only medical doctors, specialized in eye diseases, have the professional knowledge and skills to manage the risks linked to fluorescein
- Only ophthalmologists should therefore be allowed to prescribe fluorescein as well as oversee its use by other eye care providers

Data shows that non-diagnostic use of fluorescein (e.g. for the fitting of contact lenses) represents only a very small part of the overall use, which therefore does not justify a change of classification.

- About 90% of contact lens fittings are performed with soft and disposable contact lenses where the use of fluorescein is prohibited because it will irreversibly dye the soft contact lens
- Not more than 10% of fittings are done with rigid contact lenses, where fluorescein is used
- Rigid contact lenses are mainly fitted on eyes suffering from an ocular pathology (keratoconus, orthokeratology, after ocular traumatisms or unsatisfactory cataract or refractive surgery). In those cases, rigid contact lens fitting should always occcur under the guidance of an ophthalmologist

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Fluorescein paper strips are also used to measure the intra-ocular pressure by Goldmann applanation tonometry. However, other safe methods can be used by eye care providers to measure intraocular pressure, for which fluorescein is not necessary.

- Intraocular pressure measurement is one of the parameters to diagnose and follow-up glaucoma patients
- One of the methods to measure intra-ocular measure is Goldmann applanation tonometry, where the tonometer flattens the cornea after instillation of an anesthetic eye drop
- This method is still considered the gold standard but eye care providers can also reliably assess the intraocular pressure by a non-contact method, e.g. air-puff tonometry where fluorescein is not necessary

Given the use of fluorescein paper strips mainly as a diagnostic tool, the importance of an ophthalmologist supervising the use of fluorescein as well as the limited cases of use of fluorescein for fitting of contact lenses, there is no justification for a change of classification of fluorescein paper strips from medicinal product to medical device.

Background

As a result of the October 2012 meeting of the Borderline and Classification Medical Devices Expert Group, the European Medicines Agency (EMA) issued a Scientific Opinion on fluorescent ophthalmic strips. The opinion has been made available in January 2013 and concludes that fluorescent ophthalmic strips fall under the definition of a medicinal product. Following the publication, a number of organisations challenged this scientific opinion and called for the introduction of a dual classification for fluorescent ophthalmic strips taking into account the use of fluorescent ophthalmic strips for non-diagnostic purposes.

The Borderline and Classification Medical Devices Expert Group is expected to reach an agreement on the definition of fluorescent ophthalmic strips at an upcoming meeting. This opinion will not be binding for EU member states.

References

[1] EU (2010) Meddev 2. 1/3 Rev 3 –Guidelines relating to the application of: The Council Directive 90/385/EEC On Active Implantable Medical Devices; The Council Directive 93/42/EEC On Medical Devices; available at: http://www.meddev.info/_documents/2_1_3_rev_3-12_2009_en.pdf

[i] European Glaucoma Society (EGS), European Eye Bank Association (EEBA), European Society of Retina Specialists (EURETINA), European Association for the Study of Diabetes (EASDec), European Paediatric Ophthalmology Society (EPOS), European Society of Cataract and Refractive Surgeons (ESCRS), European Association for Vision and Eye Research (EVER), European Society of Cornea & Ocular Surface Disease Specialists (EUCORNEA), European Vision Institute (EVI)