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Press Office

Press release

European and international experts discuss the way forward in developing ophthalmology medicines

European Medicines Agency hosts first workshop on medicines for eye disorders

On 27 and 28 October 2011, the European Medicines Agency assembled for the first time some 200 experts in eye diseases from Europe, Australia, Japan and the United States of America in a two-day workshop. The attendees reviewed regulatory and scientific challenges in developing medicines for eye disorders.

New treatments in ophthalmology are rapidly evolving, with the recent breakthrough of new medicines for wet age-related macular degeneration. Research is also ongoing in new eye diseases where no treatment is yet available, such as retinitis pigmentosa and dry age-related macular degeneration.

The workshop participants, who included European regulators, the pharmaceutical industry, doctors and patient representatives, discussed methods for measuring visual function in clinical trials, developing stem cells and gene therapy for retinal diseases, treatment for macular diseases and inflammation in the eye, repairing the corneal surface with stem cells and treatment for dry eyes.

The participants also tackled the development of treatment in childhood eye disorders such as retinal diseases in premature babies, childhood glaucoma, eye inflammation and relief of pain after eye surgery. Particular challenges relate to measuring outcomes in children, the absence of good-quality information on existing treatments used in areas such as eye inflammation, and the need for long-term safety data.

“The workshop was successful in developing interactions between European regulators, doctors and patient representatives and pharmaceutical industry in this area,” said Spiros Vamvakas, Head of Scientific Advice at the Agency. “We will now move forward with regulatory guidance in areas such as dry eyes and macular oedema - swelling in the back of the eye - which will require further stakeholder input.

“Further discussion and research is needed before we can provide guidance in other areas such as trial designs and endpoints in inflammation of the eye, and advanced therapies in corneal and retinal disease.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

“The workshop identified the need for future submissions for endpoints and biomarker qualifications from companies, academia or consortia and we are looking forward to receiving these. We also encourage companies developing eye products to come and discuss their development plans with us at an early stage.”

The Agency will continue its public dialogue with academia, regulators, pharmaceutical industry, doctors and patients’ representatives on ophthalmology medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The presentations of this workshop, together with a summary report, will be published on the Agency’s website shortly.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu