



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 June 2011  
EMA/375555/2011  
Human Medicines Development and Evaluation

## Draft agenda EU regulatory workshop in ophthalmology

27-28 October 2011 Clinical development, scientific advice

28 October 2011 Paediatric investigation plans

European Medicines Agency, London, United Kingdom

### **Background for workshop on clinical development and scientific advice in ophthalmology**

Ophthalmology is an evolving area, especially with a growing elderly population together with recent breakthroughs (e.g. intravitreal VEGF-inhibitors). Several medicinal products are in clinical development, which of some in 'new' ophthalmological indications, i.e. indications where no satisfactory treatment options are available. Such indications are emerging, for example, in retinal degenerations such as dry AMD, and Meibomian gland dysfunction. Other such diseases like retinitis pigmentosa are targeted by cell or gene therapy. Besides requiring complex clinical trials, in a number of these diseases, efficacy endpoints are not yet established.

### **Aims**

The workshop is focused on clinical development and methodological issues, including the choice of outcome measures, and trial design. The workshop aims to

- Consider upcoming regulatory and scientific challenges relating to ophthalmology medicinal products which may be submitted to the European medicines Agency (EMA) scientific advice working party (SAWP) and the Committee for Medicinal Products for Human Use (CHMP)
- Develop interactions between the European regulatory network in ophthalmology / and with academia/clinical experts
- Promote understanding of CHMP's work in the field of ophthalmology
- Consider outputs for ophthalmology as a regulatory therapeutic area e.g. concept papers

The workshop will bring together European regulators, clinical ophthalmologists and pharmaceutical industry representatives working in early to late clinical product development in ophthalmology.



Experts and stakeholders interested in attending should send an expression of interest using [the registration form to eye2011@ema.europa.eu](#) by 24th July 2011. No more than 2 representatives per organisation should be submitted. Note that spaces will be limited and the workshop will be open to EMA confirmed attendees only. The outcome and presentations will be published on the EMA website. No fee will be charged for this meeting.

## **Background for workshop on paediatric investigation plans**

In 2007, The European Union's Paediatric Regulation established new responsibilities for the Agency in the field of paediatric medicines. These responsibilities included the establishment of a paediatric Committee (PDCO), and the determination of studies that companies must undertake on children as part of paediatric investigation plans (PIPs). In the European Union (EU), children are defined as persons from birth up to 18 years of age.

Other roles of the PDCO involve establishing and regularly updating an inventory of paediatric medicine needs, and advising and supporting the development of the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA).

Some experience has now been gained with PIPs for products in ophthalmology indications.

Therefore this workshop aims to bring together regulators, clinicians and industry to consider PIPs in this therapeutic area, examine priorities for unmet pharmacological needs in paediatric ophthalmology, and consider critical issues of clinical trial design and development in these indications.

Expression of interest in attending can be made via the registration form to [eye2011@ema.europa.eu](mailto:eye2011@ema.europa.eu) by 24th July 2011. Note that spaces will be limited and the workshop will be open to EMA confirmed attendees, who have also registered for the 2 day workshop. No more than 1 representative per organisation will be permitted. This meeting will be in parallel to the afternoon session of the 28<sup>th</sup> October 2011. Registration is no guarantee of a place. No fee will be charged for this meeting.

## Day 1 - Thursday 27 October 2011

Chair: Dr Eric Abadie, Chair of CHMP

Time	Presentation title	Presenter/ affiliation
08:30	<b>Registration and coffee</b>	
09.00	<b>Introduction/Welcome</b>	Eric Abadie, Chair Committee for Medicinal Products for Human Use, Scientific Advisor to the General Director, AFSSAPS, Paris, France
	<b>Visual function endpoints in clinical trials</b>	Clinical, Industry and regulatory speakers
	<b>Advanced therapy in retinal disease</b> Gene therapy and stem cell therapies	Clinical/ Industry and regulatory-Committee advanced therapies/committee orphan diseases speakers
	<b>Macular oedema (DMO, RVO)</b>	Clinical, Industry and regulatory speakers
	<b>Dry AMD</b>	Clinical, Industry and regulatory speakers
17:30	<b>End</b>	E

## Day 2 – Friday 28 October 2011

Chair: Mr Robert Hemmings, Chair of SAWP

Time	Presentation title	Presenter/ Affiliation
08:30	<b>Registration and coffee</b>	
09.00	<b>Introduction to Day 2</b>	Robert Hemmings, CHMP member, Chair Scientific Advice working Party EMA, Head of statistics, MHRA
	<b>Intraocular inflammation</b>	Clinical, Industry and regulatory speakers
	<b>Corneal Disease</b> Prevention of corneal graft rejection, Limbal stem cell therapy	Clinical, Industry and regulatory speakers
	<b>Parallel Sessions</b>	<b>Dry Eyes</b> 13:50 – 17.30 <b>Paediatrics</b> 13:40 – 17.30
	<b>Dry eye -DEWS update, Meibomian Gland Dysfunction, Ocular surface biomarkers and inflammation</b>	Clinical, Industry and regulatory speakers
	<b>Questions &amp; Answers Panel Discussion (pre submitted questions)</b>	Panel of regulators
17:30	<b>End</b>	

## Day 2 – Friday 28 October 2011 PM only, parallel session

Chair Daniel Brasseur Chair of PDCO

Time	Presentation title	Presenter/ Affiliation
13:40	<b>Introduction</b>	Chair
	<b>Childhood blindness and visual impairment</b>	Clinical and regulatory speakers
	<b>Overview of paediatric legislation and PDCO ophthalmology activity</b>	
	<b>Anterior segment</b>	Clinical and regulatory speakers, panel on presubmitted questions
	<b>Uveitis</b>	Clinical and regulatory speakers, panel on presubmitted questions
	<b>Glaucoma</b>	Clinical and regulatory speakers, panel on presubmitted questions
	<b>Other e.g. ROP</b>	Clinical and regulatory speakers, panel on presubmitted questions
17.30	<b>End</b>	