Reviewer's report

Title: Ocular Medicines in Children

Version: 1 Date: 29 June 2011

Reviewer: Lise Aagaard

Reviewer's report:

The purpose of this manuscript is to compare the availability and the licensing status of ocular medications marketed in Italy, the United Kingdom (UK), the United States, and evaluate the evidence on safety and efficacy of these drugs in the paediatric population.

The article is important to clinicians, however I do not think that the second part of the aim is answered in this article. The authors' only list the number of RCT's located in the literature, but no results on efficacy and safety is reported from these studies.

The authors' do not state either why the countries Italy, the UK and the United States is choosen as cases. Other countries might have been more relevant, since the licensing practice is obviously differing between countries.

Specific comments:

Title: The present title should be reformulated so it reflects the design and content of the study.

Materials and methods: It is not stated whether the pharmaceutical companies producing the medications or the local regulatory agencies were contacted to search for information about studies used for licensing of the ocular medications. Since many clinical trials are never published it would have been relevant to contact these stakeholders for more information.

Results: A large number of RCTs are mentioned, but were they used for licensing the medications, or are they just Fase IV studies? These RCTs should be listed in the reference section, and therefore this section lacks literature references.

The section reporting findings from the guidelines does not tell at which level of evidence the paediatric guidelines were recommended.

Discussion: This section is uninterested, as no clinical or efficacy parameters are discussed.

Conclusion: This section is too long. I think the majority of this section belongs to the introduction. In this sections the authors' should only conclude on the study results.
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

'I declare that I have no competing interests'