Reviewer's report

Title: Ocular Medicines in Children

Version: 1 Date: 18 July 2011

Reviewer: Adriana Ceci

Reviewer's report:

Minor Essential Revisions

1. We suggest to better clarify that PIPs approved by the EMA and the list of paediatric variations approved by FDA are two very different non-comparable instruments. In fact, the first are developmental plans that identify the clinical research to be performed and mainly deal with new (unapproved) drugs; on the other hand, the FDA lists provide already approved changes in response of FDA written requests and deal with old and already marketed drugs. To make data more comparable, the AA should include in their analysis also the "List of the active substances included in the work-sharing procedure (available at http://www.hma.eu/99.html) set up in accordance with Articles 45 and 46 of the European Paediatric Regulation and evaluating medicinal products available on the market.

2. The reference to the cited work-sharing procedure should be part of the conclusions of this paper as it represents a valuable attempt to reduce Member States differences both in terms of off-label use and of use of drugs in lack of clinical experimental evidence.

Discretionary Revisions

1. The interpretation of results could be facilitated by using tables and graphics.

2. The approved paediatric status in lack of paediatric studies should be discussed also underlying that age approval is under the direct responsibility of the National Authorities and that the Paediatric Regulation specifically aims at reducing this authorized, but not scientifically validated uses. However, the results of the comparison should be better reflected in the discussion and conclusions.

3. Of particular interest in this paper is the analysis of the paediatric guidelines. Nonetheless, we suggest to better elucidate the results of this analysis. In particular, the number and the details of drugs that are ‘recommended while not licensed’ should be given in order to stimulate new studies and funds.

4. The safety risk claimed in the discussion could be better substantiated in the light of the licensed status of some drugs for which no paediatric studies have been performed. The registrative status of decongestant (sympathomimetic) agents in Italy should be underlined (Oxymetazoline, Tetryzoline) as an example.

Level of interest: An article of importance in its field
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.