Reviewer's report

Title: A multicentre, randomised, double-blind, single-dose study comparing the efficacy of Strepsils Warm lozenge or Strepsils Cool lozenge with a non-medicated lozenge in the relief of acute sore throat

Version: 1 Date: 6 July 2010

Reviewer: Ronald Eccles

Reviewer's report:

The study investigates the effects of three lozenges on sore throat symptoms. Two of the lozenges contain either cooling or warming agents plus antibacterial/antivirals and the effects of these two lozenges are compared with a sugar base lozenge. The use of cooling and warming agents in common cold medicines is an important area of research as cooling and warming sensations can influence how the patient appreciates the efficacy of a medicine as they have a great sensory impact. Cooling and warming agents are widely used in cough medicines and in throat lozenges to provide a powerful sensory signal that may indicate to the patient a powerful treatment effect and enhance any placebo effect of the treatment. The results of the present study clearly demonstrate that medicated lozenges with cooling or warming sensates provide a greater relief of symptoms than a non flavoured lozenge without medication. It is not possible from the design of the study to determine if it is the flavouring or the medication that provides symptom relief. The authors regularly refer to comparisons between the medicated and the non-medicated lozenges but in fact the patient is also comparing powerfully flavoured lozenges with cooling and warming actions to an insipid sugar control lozenge. The study is not truly blinded as blindfolding the patients will not mask any cooling or warming sensation. Presumably the patients were informed about the aims of the study in the patient information leaflet and they would immediately know which lozenge they were given because of the cooling and warming sensations.

In general I am impressed by the results and believe they are a very interesting and useful addition to the literature on the treatment of sore throat by cooling and warming agents.

Major Compulsory Revisions

1. It should be made clear that the design of the study does not allow any conclusion that the medications in the lozenges were responsible for the effects found in the study. If the authors wish to claim that the medications were effective then the correct comparison would be between unflavoured medicated lozenges versus identical unflavoured lozenges without any medications.

2. The paper should discuss the sensory impact of the lozenges and the likely impact of this in enhancing a placebo effect on sore throat symptoms.

3. I am not sure about the policy of the journal as regards promoting proprietary
names but it is not really necessary to use the proprietary name of the product-Strepsils – in the title and throughout the paper. The proprietary name could be mentioned in the methods but the clinical importance of the paper is in comparing different formulations of lozenges.

4. The blinding of the study should be discussed – were any attempts made to determine if the patients knew which type of lozenge they were administered. My own view is that the study is unblended. Some information should be given about what the patient information contained as regards the cooling and warming aspects of the lozenges- was this mentioned in the PIL?

Minor Essential Revisions

It would be useful to know the exact composition of the cooling and warming flavourings. Many cooling and warming agents have pharmacological effects. Menthol is a cooling agent with local anaesthetic actions and capiscum which is sometimes used as a warming agent interacts with nociceptors and could influence the sensation of pain etc.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests