Reviewer's report

Title: Clinically relevant safety issues associated with St. John’s wort product labels

Version: 2 Date: 2 June 2008

Reviewer: Rainer Ludtke

Reviewer's report:

Dear Editor,

this is a interesting analysis on how safety issues on SJW are dealt with in drug labels. I have, however, some major points concerning the statistics used.

1. My major point is a very general one: as far as I understood the paper there was one single score (ranging from 0 to 8) for each of the 74 SJW drugs. Thus, there is no need to compare two drugs by means of statistical analysis: two scores are either different, or they are not. There is no uncertainty in the data. I thus believe that reporting simple scores is enough, there is no statistics needed.

2. In case I did not understand fully how the products were scored and there indeed are multiple ratings for each product, the statistical methods need some revision:

   a. This paper analyses numbers ranging from 0 to 8, which clearly is an ordinal scale, but not a continous nor a nominal scale. Consequently, neither ANCOVA models (which fit normally ditributed data) nor chi-square tests (which are useful for nominally distributed data) are appropriate to analyse the data. I recommend to use either Kruskal-Wallis tests or to fit Poisson-models to the data.

   b. Moreover, in this paper the Duncan test was used to compare pairs of SJW-products. Generally, the Duncan test is not recommended at all because it does not control the multiple nor the global level of significance. I thus suggest to use alternative methods of multiple testing, e.g. a Bonferoni-Holm procedure which can be easily implemented with the data.

Although this article is of no interest for an European like me, I recommend to accept the paper after the above mentioned points of criticism have been considered.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests