Reviewer's report

Title: Burden of paediatric rotavirus gastroenteritis (RVGE) and potential benefits of a universal Rotavirus vaccination programme in Spain

Version: 1 Date: 15 February 2010

Reviewer: Hanna Maria Nohynek

Reviewer's report:

This is an important and timely paper on the burden of pediatric rotavirus gastroenteritis and the potential benefits of a universal rotavirus vaccination in Spain. At the end of the Introduction, the authors declare that the study was not a formal cost effectiveness analysis, rather a study exploring with a health-economic cohort model the costs and health benefits of the universal introduction of a certain rotavirus vaccine.

- Major Compulsory Revisions

1. Why is only one vaccine (the pentavalent rotavirus vaccine, RotateqR manufactured by sanofi Pasteur) being addressed in this study? From the public health perspective there is still very little evidence to suggest that there are such major differences in the effectiveness of the two available rotavirus vaccines that it justifies addressing only one in this kind of a burden vs. benefit paper for one country. The messages would be more relevant and the paper more attractive to the wider public health and scientific audiences, including decision makers in Spain and in the different European countries as well as elsewhere, if the study concentrated on rotavirus vaccination in general, and then factored in the potential differences of the mono vs. pentavalent preparations (epidemiological coverage, price, duration of protection) in the sensitivity analysis.

2. Clarifications in the model inputs for epidemiological data are needed, since any model of this kind is very sensitive to the assumptions made (as the authors rightly acknowledge in the discussion). How representative of all Spain is the Spanish data selected from the REVEAL study and used for the model in this paper? Two hospitals, three ERs and 23 PCCs including 801 children seem a very small number. This should be addressed in more detail than now is done.

3. Why was per protocol efficacy data of rotavirus vaccine used in the model? PP VE usually reflects the best possible efficacy estimate obtained from gold standard settings of randomized controlled trials. A closer to real life estimate would have been the intent to treat VE. Please clarify.

4. Rota vaccination related adverse events were not taken into consideration at all. Why?

- Minor Essential Revisions

• Discretionary Revisions

None.

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

**Quality of written English:** Needs some language corrections before being published

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

**Declaration of competing interests:**

In the past five years, I have received compensation from pharmaceutical industry for participating in scientific advisory boards (pneumococcal vaccination), and from lecturing or chairing scientific sessions sponsored by pharmaceutical industry (pneumococcal vaccination, travel related vaccines).