



Response to NICE consultation document on Rimonabant for the treatment of overweight and obese adults

About the Faculty of Public Health

The Faculty of Public Health is the leading professional body for public health specialists in the UK. It aims to promote and protect the health of the population, and improve health services, by maintaining professional and educational standards, advocating on key public health issues, and providing practical information and guidance for public health professionals.

Comments

Thank you for inviting the Faculty of Public Health to comment on the consultation document on Rimonabant. The Faculty supports the view expressed by NICE that rimonabant should not be recommended for the treatment of obese and overweight adults. In particular, we wish to highlight the following issues:

1. The cost-effectiveness of rimonabant has been calculated against placebo. All the comparisons with other weight loss drugs have been extrapolated from other studies. We agree with NICE that these calculations are open to considerable error.
2. The durability of treatment effect appears limited and the data provided shows a diminishing effectiveness of treatment in the second year. Hence we are particularly concerned at the assumption that treatment benefits are maintained in the longer term.
3. There is clear evidence that weight gain results if rimonabant is discontinued. It is likely, therefore, that this drug would need to be used for considerably longer than a year. Long-term evidence on efficacy and safety is lacking.
4. The safety of rimonabant with respect to mental health requires further exploration. The FDA Briefing Document (June 2007) demonstrates that there is a small but significant increase in mental health problems in those on 20mg of rimonabant.
5. Further, the FDA document also suggests that these adverse effects continue into the post-marketing phase and we are concerned that the associated costs of treatment for mental health problems may have been under-estimated. This would have a considerable influence on the ICER of this drug. We were unclear about the exact studies used for comparison with other drugs.
6. Given the significant evidence for psychiatric adverse events for patients treated with Rimonabant, as described by the US Food and Drug Administration, we are of the view that this should have been reflected in the structure and parameterisation of the model.

7. We are also concerned at the data sources used to estimate health state utilities in the model. The use of the Health Survey for England (HSfE) seems appropriate. Our understanding is the HSfE includes the data necessary to establish cardiovascular status. We are therefore surprised that a separate data source, HODAR, was used to estimate the utilities (decrements) in the CVD and Diabetes States. The submission does not explain why HODAR was chosen over alternative data sources; nor does it provide information on the impact of using alternative data sources on the results.
8. The regression model used to estimate age-specific utilities will generate utility values in excess of 1.0. It has been estimated with no regard to the underlying theoretical construct. The submission does not provide adequate information on why this model was chosen, or even whether any alternative models were tested. Given that the utility values are frequently highly influential parameters in a cost effectiveness model, we are unconvinced that these utility values are fit for purpose. Further, we believe that age-specific UK Norms for the EQ-5D are available from the Measurement and Valuation of Health Study team at the University of York, and are therefore surprised that these were not used in the analysis.
9. The majority of the parameters in the cost effectiveness analysis have not been included in the probabilistic sensitivity analysis – including the age-specific utilities, the utility decrements for the other disease states, and, as far as we can tell, the impact of changes in BMI on the risk of developing CVD and Diabetes. As a result it is certain that the results of the sensitivity analysis substantially understate the true degree of uncertainty around the ICER; and likely that if an appropriate PSA was undertaken, the expected ICER would be substantially different to that reported.
10. Whilst we recognise that NICE must not consider affordability, it must consider opportunity cost. The potential demand for this drug is large and the opportunity cost of mandating its provision substantial. The clinical significance of the health gain from Rimbonant does not appear to be of sufficient magnitude for the NHS to be confident that it will only displace less valuable uses of its limited resources.
11. Given the potential opportunity cost of a positive recommendation, it is likely that additional research to address the uncertainties in the evidence on the cost effectiveness of Rimbonant would be an efficient use of resources.
12. The treatment of obesity should not be over medicalised and much more attention needs to be placed on the social and psychological aspects of obesity prevention and management. It is the professional view of the Faculty of Public Health, based on the experience of our members, that the implementation of sibutramine and orlistat has not had a demonstrable effect on the prevalence of obesity in PCT populations.

In conclusion, we are supportive of the view expressed by NICE that rimonabant should not currently be recommended for the treatment of obese and overweight adults.