



Wednesday, September 26, 2012

[REDACTED]
[REDACTED]
[REDACTED] Centre for Health Technology Evaluation
National Institute for Health and Clinical Excellence
Manchester

Re: NICE Decision Support Unit (DSU) report: Consideration of bevacizumab as a comparator in the appraisal of Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO).

[REDACTED]

Thank you very much for the opportunity to comment on the report of additional work commissioned by NICE to the Decision Support Unit (DSU), relating to the consideration of bevacizumab as a comparator in the appraisal of Ranibizumab for the treatment of macular oedema caused by RVO. Allergan welcomes this opportunity and would like to make the following points:

- The manipulation to break down doses of bevacizumab in smaller amounts is inappropriate. MHRA legislation does not permit the manipulation of even a licensed medication under a "specials" exemption if there is an equivalent licensed product available
- Bevacizumab is not licensed for RVO. Allergan feels that as a manufacturer of branded, research-intensive products we do not support the inclusion of comparators which have not been subject to analogous rigorous clinical development and evaluation in the relevant indications
- In general, the report demonstrates the need for large scale, rigorously conducted, randomized trials in diabetic macular oedema (DMO) and RVO to support an assessment of bevacizumab in these disease areas. The typically small size, high degree of heterogeneity, mixed level of rigor and often limited study duration limit the inferences which can be reliably drawn from this data.

Allergan remains fully committed and interested to actively participate as a stakeholder for all RVO submissions, based on the fact that Ozurdex® is the only product recommended by NICE to treat RVO and in the interest of all patients who could benefit from treatment for this devastating condition.

ALLERGAN



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We look forward to hearing from you in due course and continuing this dialogue as necessary.

Yours sincerely,



(HEPRA) - Ophthalmology
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