Draft Version – out of date as of 23 June 08

**Novartis Pharmaceuticals UK Limited**
**Revised Outline Proposal for Dose Capping Scheme for Ranibizumab (Lucentis®)**
**for the treatment of patients with Wet AMD**

**January 14th 2008**

**Prepared by XXXXXXXXXXXXXXXXXXXXXXXXXXX  Novartis Pharmaceuticals UK Ltd)**

**The revised proposal outlined below is based on discussions between Novartis, NICE and DH that occurred on December 20th 2007 following publication of the Appraisal Consultation Determination in respect of this technology appraisal.**

**Outline of Revised Proposal**

The proposal is for an individual patient based scheme, whereby Novartis would provide reimbursement if the actual injection frequency with ranibizumab exceeds a total of 14 injections per treated eye for the period during which the scheme operates. Hence the NHS would fund up to and including 14 injections per treated eye, whilst Novartis would provide reimbursement for injections 15 and beyond and would reimburse for drug costs only at NHS list price.

To be included in the dose capping scheme, ranibizumab must be administered in accordance with its summary of product characteristics particularly with respect to the licensed indication and frequency of administration. Any deviation from these requirements would exclude such patients from the scheme.

As discussed with NICE and DH and in accordance with DH principles regarding 'risk sharing' schemes, Novartis Pharmaceuticals UK Limited would enter into a contractual agreement with the NHS to provide reimbursement to the NHS if any individual patient required greater than 14 injections per treated eye in accordance with the conditions of the scheme.

This contract would be effective until the review date of the forthcoming NICE technology appraisal guidance.  Both parties would have the option to terminate the contract and end the 'dose capping' scheme at any time on notice.

Any additional data collection such as that proposed by the RCO would be distinctly separate from the dose capping scheme and would not be mandatory.

A detailed process flow for the scheme is in development and will be shared with NICE/DH following finalization.