Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 December 2003 please refer to module 8B.

- On 27 September 2000 the MAH submitted a Type II variation (II/01) to extend the clinical indication, mainly to include the treatment of subfoveal CNV due to pathological myopia. In addition, the opportunity was taken to amend the SPC with regard to pre-clinical safety information, and with updated clinical safety information arising from post-marketing safety studies and PSUR reports. The CPMP gave a positive opinion on this variation on 14 December 2000, and the Commission Decision was issued on 20 March 2001.
- On 30 November 2000, the EMEA issued a Notification of approval for a Type I variation (I/02) to change the name of the MAH from CIBAVision Europe Ltd to Novartis Ophthalmics Europe Ltd, together with a change of address. The corresponding Commission Decision was issued on 16 February 2001.
- On 16 February 2001, the EMEA issued a Notification of approval for a Type I variation (I/03) to change the analytical test method for the average particle size assay of the finished product.
- On 27 June 2001, the EMEA issued a Notification of approval for a Type I variation (I/04) to extend the shelf life from 2 years to 3 years. This change was incorporated in the Annexes of the CPMP opinion for the Type I variation above, and in the Commission Decision of 10 September 2001.
- On 7 November 2001, the EMEA issued a Notification of approval for a Type I variation (I/06) to extend the retest period of the active substance from 24 months to 36 months at the approved storage conditions.
- On 5 November 2001 the MAH submitted a Type II variation application (II/07) to add an additional manufacturer and to make changes to the manufacturing process. The CPMP gave a positive opinion on this variation on 17 January 2002, and the Commission Decision was issued on 11 February 2002.
- On 10 December 2001 the MAH submitted a Type II variation application (II/08) to update sections 4.4 and 4.8 of the SPC and the corresponding section 4 of the Package Leaflet as requested by the CPMP following the assessment of the second PSUR. Furthermore, the same sections are revised following the assessment of the data submitted as follow up to the first PSUR. The CPMP gave a positive opinion on this variation on 21 February 2002, and the Commission Decision was issued on 24 May 2002.
- On 10 September 2001 the MAH submitted a Type II variation application (II/05) to extend the therapeutic indication to include the indication of occult subfoveal choroidal neovascularisation due to age-related macular degeneration. The CPMP gave a positive opinion on this variation on 30 May 2002, and the Commission Decision was issued on 22 August 2002.
- On 10 December 2001 the MAH submitted a Type II variation application (II/09) for an update of sections 5.1 of the SPC to add the clinical results of study BPD OCR 003 PM at 24 months. The CPMP gave a positive opinion on this variation on 30 May 2002, and the Commission Decision was issued on 22 August 2002.
- On 5 September 2002, the EMEA issued a Notification of approval for a Type I variation (I/10) to introduce minor changes in manufacture of the medicinal product.
- On 9 September 2002 the MAH submitted a Type II variation application (II/12) to apply for a change of in-process controls of the finished product and to discontinue two sample tests. The CPMP gave a positive opinion on this variation on 21 November 2002, and the European Commission acknowledged receipt on 27 November 2002.

- On 4 December 2002, the EMEA issued a Notification of approval for a Type I variation (I/13) to change the packaging site (labelling and secondary packaging), batch control site, and batch release site from Laboratories CIBA Vision Faure, Annonay, France, to Novartis Pharma S.A.S., Huningue, France. In addition, Novartis Ophthalmics applied for a change of the local representative in France from Novartis Ophthalmics S.A., Rueil-Malmaison to Novartis Pharma S.A.S., Rueil-Malmaison. The Commission Decision was issued on 14 January 2003.
- On 8 July 2003 the Marketing authorisation Holder submitted an application for the transfer of the Marketing Authorisation for Visudyne from Novartis Ophtalmics Europe Ltd. to Novartis Europharm Limited, United Kingdom. The transfer was approved by the EMEA on 4 August 2003. The EMEA notified the European Commission, who amended the Commission Decision on 22 September 2003.
- On 17 November 2003, the EMEA issued a Notification of approval for a Type IB variation (I/15) to introduce minor changes in manufacture of the finished product.