Steps taken after granting the Marketing Authorisation

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

- In accordance with Article 10(3) of Council Directive 92/27 EEC of 31 March 1992, the EMEA issued on 4 February 1999 a Notification for deletion of the second repetition of the term 'eye drops solution' on the labels and in addition minor linguistic changes to the package leaflets. The Commission amended the Commission Decision on 16 March 1999.

- The Marketing Authorisation Holder submitted on 15 February 1999 a Corrigendum to the Danish SPC in order to rectify the missing shelf life in section 6.3. The Commission amended the Commission Decision on 4 March 1999.

- On 13 March 2000 the Marketing Authorisation Holder submitted an application for a Type I variation relating to a change of the manufacturing sites for part or all of the manufacturing process of the medicinal product. The procedure started on 15 March 2000. The EMEA on 24 March 2000 approved this variation, which required amendments to the Commission Decision. The European Commission amended the Decision on 31 May 2000.

- On 11 July 2000 the Marketing Authorisation Holder submitted 6 applications for Type I variations. Three variations relate to a change in test procedure of active substance. The fourth variation is for an extension of the retest period of the active substance and the fifth variation is a change in the name of a manufacturer of the active substance. The procedure for the first five variations started on 13 July 2000. The sixth variation is a minor change of manufacturing process of the active substance. Additional information for this variation was requested and the procedure for this variation started on 17 July 2000. On 4 August 2000 the EMEA approved all six variations, which did not require amendments to the Commission Decision.

- On 15 May 2001, the Marketing Authorisation Holder submitted an application for EMADINE 0.05% eye drops, solution, single-dose container pursuant to Article 2(1) of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, and Annex II point 3 (iv). The CPMP during its February 2002 plenary meeting considered the application acceptable and issued on 21 February 2002 a positive Opinion for granting a Marketing Authorisation for EMADINE 0.05% eye drops, solution, single-dose container. The corresponding Commission Decision was issued on 30 May 2002.

- On 20 March 2002 the Marketing Authorisation Holder submitted an application for a Type I variation relating to a change in the manufacturing sites of part or all of the manufacturing process of the medicinal product. The EMEA issued the Notification for this variation, which required amendments to the Commission Decision, on 20 June 2002.

- On 7 October 2002, the Marketing Authorisation Holder submitted an application for a Type II variation in accordance with Art. 6 of Commission Regulation (EC) No. 542/95 as amended. The Marketing Authorisation Holder applied for an update of the SPC, Package Leaflet and Labelling in order to harmonise the multi-dose and single dose presentations of EMADINE eye drops solution and to harmonise EMADINE with the other Alcon products approved through the centralised procedure. Additionally, the Package Leaflet for the single dose presentation was amended to reflect the results of readability testing. The CPMP during its February 2003 plenary meeting considered the variation acceptable and issued on 20 February 2003 a positive Opinion on the Type II variation. The corresponding Commission Decision was issued on 19 May 2003.

- On 20 June 2003 the Marketing Authorisation Holder submitted an application for a Type I variation relating to an extension of the shelf-life of the multi-dose presentation from 2 years to 30 months. The EMEA issued the Notification for this variation, which required amendments to the Commission Decision, on 24 July 2003. The corresponding Commission Decision was issued on 16 September 2003.