**Steps taken after granting the Marketing Authorisation**

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

- On 3 December 2001, the Marketing Authorisation Holder submitted to the EMEA one application for a Type I variation related to a change in the manufacturer of the active substance (EMEA/H/C/390/I/01). The EMEA approved this variation on 6 February 2002.
- The MAH submitted on 30 January 2002 a request to introduce changes to an aspect of the Package Leaflet not connected to the SPC, in accordance with Article 61(3) of Council Directive No 2001/83/EC. This change concerned an update to the contact details of one of the local representatives and to amend some typographical errors in the German Package Leaflet. The MAH received a positive notification from the EMEA on 5 February 2002.
- On 30 January 2002 the Marketing Authorisation Holder submitted a Corrigendum to the Commission Decision dated 27 November 2001 for the French SPC (section 5.1), Finnish SPC (section 5.1) and Swedish SPC (section 5.1) and the German labelling. This Corrigendum required amendments to the relevant sections of the Commission Decision.
- On 10 May 2002, the Marketing Authorisation Holder submitted to the EMEA one application for a Type I variation related to a change in specifications of the active substance and consequential changes in test procedure of the active substance (EMEA/H/C/390/I/03). The EMEA approved this variation on 27 June 2002.
- On 12 June 2002, the Marketing Authorisation Holder submitted to the EMEA one application for a Type I variation related to a change in the manufacturer of the active substance (EMEA/H/C/390/I/04). The EMEA approved this variation on 17 July 2002.
- On 26 June 2002, the Marketing Authorisation Holder submitted to the EMEA an application for a Type II variation (EMEA/H/C/390/II/05). The Marketing Authorisation Holder applied for an update of section 4.4 of the Summary of Product Characteristics and sections 2 and 4 of the Package Leaflet following the first annual assessment of the Follow-up Measure with respect to iris colour changes. Furthermore, the MAH applied for linguistic changes to the French, Italian and Dutch Product Information. The CPMP considered the variation acceptable and issued on 22 August 2002 a positive Opinion on the Type II variation. The corresponding Commission Decision was issued on 12 November 2002.
- On 9 December 2002, the Marketing Authorisation Holder submitted to the EMEA an application for a Type I variation to extend the shelf life of the finished product from 2 to 3 years (EMEA/H/C/390/I/07). The EMEA approved this variation on 10 January 2003.
- On 9 December 2002, the Marketing Authorisation Holder submitted to the EMEA an application for a Type II variation (EMEA/H/C/390/II/06). The Marketing Authorisation Holder applied for an extension of indication for TRAVATAN to be used as first line therapy in patients with ocular hypertension and open-angle glaucoma. The Marketing Authorisation Holder also applied for amendments to the Package Leaflet concerning the instructions to the patient in relation to discontinuation and use. Furthermore, the term “watery eyes” was added to section 4 of the Package Leaflet to harmonise with the Summary of Product Characteristics. The contact details of the Icelandic local representative were updated in the Package Leaflet. The CPMP considered the variation acceptable and issued on 25 April 2003 a positive Opinion on the Type II variation. The corresponding Commission Decision was issued on 28 July 2003.
- On 16 April 2003, the Marketing Authorisation Holder submitted to the EMEA an application for a Type I variation to change the name of the manufacturer of the active substance (EMEA/H/C/390/I/08). The EMEA approved this variation on 19 May 2003.
- On 4 August 2003 the Marketing Authorisation Holder submitted a Corrigendum to the Commission Decision dated 28 July 2003 for the Dutch, French and Spanish SPC (sections 4.1, 4.4 and 4.8.). This Corrigendum required amendments to the relevant sections of the Commission Decision.

- On 16 May 2003, the Marketing Authorisation Holder submitted to the EMEA an application for a Type II variation (EMEA/H/C/390/II/09). The Marketing Authorisation Holder applied for an update of section 4.8 of the Summary of Product Characteristics and sections 2 and 4 of the Package Leaflet following the assessment of the second Periodic Safety Update Report (PSUR). The CPMP considered the variation acceptable and issued on 24 July 2003 a positive Opinion on the Type II variation. The corresponding Commission Decision was issued on 24 October 2003.