Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 June 2004 please refer to module 8B.

- On 15 April 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in pack size. The EMEA issued the Notification for this variation on 17 May 2002.
- On 15 April 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to changes in the manufacture of the medicinal product. The EMEA issued the Notification for this variation on 17 May 2002.
- On 15 April 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in container shape. The EMEA issued the Notification for this variation on 17 May 2002.
- On 15 April 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in storage conditions. The EMEA issued the Notification for this variation on 17 May 2002.
- On 30 August 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a withdrawal of the manufacturing authorisation for a site of manufacture. The EMEA issued the Notification for this variation on 1 October 2002.
- On 30 August 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in the name the marketing authorisation holder with a consequential change in the name of manufacturer. The EMEA issued the Notification for this variation on 1 October 2002.
- On 4 March 2003, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a minor change in the manufacture of the medicinal product. The EMEA issued the Notification for this variation on 8 April 2003.
- On 12 May 2003, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in test procedures of the medicinal product. The EMEA issued the Notification for this variation on 16 June 2003.
- On 24 June 2003, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in container shape. The EMEA issued the Notification for this variation on 5 August 2003.
- On 16 April 2003, 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 extension of the therapeutic indication for first line therapy. The CPMP during its October 2003 plenary meeting considered the variation acceptable and issued on 22 October 2003 a positive Opinion on the Type II variation. The corresponding Commission Decision was issued on 20 January 2004.
- On 24 October 2003, the Marketing Authorisation Holder submitted a Type IA Variation in accordance with Commission Regulation (EC) No. 1085/2003. The variation related to a change in any part of the packaging material not in contact with the finished product. The EMEA issued the Notification for this variation on 5 November 2003.

- The MAH submitted on 14 April 2004 a request to introduce changes to an aspect of the Labelling not connected to the SPC, in accordance with Article 61(3) of Council Directive 2001/83/EC, as amended. This change concerned a change to the outer carton. The notification letter from the EMEA informing the MAH that the changes proposed were acceptable was dated 10 May 2004.