STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- On 19 March 1999 the Marketing Authorisaton MAH submitted an application for a Type I variation relating to change the name of the manufacturer of the finished bulk capsules. The packaging and release site for the EU is the same as in the original application and is not affected by this variation. The procedure started on 25 March 1999. The EMEA on 23 April 1999 approved this variation, which did not require any amendments to the Community Marketing Authorisation.
- On 30 March 1999 the MAH submitted an application for a Type I variation relating to the modification of the registered method for measurement of degradation products and impurities. The procedure started on 6 April 1999. On 29 April 1999 the EMEA approved this variation, which did not require any amendments to the Community Marketing Authorisation.
- On 6 December 1999 the MAH submitted Type I variations to introduce an additional pack size of 100 capsules to facilitate Unit Dose Administration (individual blisters packaged in perforated strips in pack sizes of 100) and to introduce an alternative packaging site for packaging and release of the unit dose preparations. The procedure started on 8 December 1999. The EMEA on 20 December 1999 approved these variations, which required amendments to the Community Marketing Authorisation. The respective Commission Decision was issued on 9 March 2000.
- In accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992, the EMEA issued on 12 April 2000 a notification to implement minor corrections to the labelling and Package Leaflet (PL). The respective Commission Decision was issued on 31 May 2000.
- On 11 October 2000, the MAH submitted an application for a Type II variation in accordance with Article 6 of Commission Regulation (EC) No 542/95 as amended. The MAH applied for an update of Section 4.5 of the Summary of Product Characteristics (SPC), based on new data from an interaction study between zaleplon and erythromycin etylsuccinate. The procedure started on 20 October 2000. The CPMP adopted a positive Opinion for this variation on 14 December 2001. The respective European Commission Decision was issued on 20 March 2001.
- On 7 November 2000, the MAH submitted an application for a Type II variation in accordance with Article 6 of Commission Regulation (EC) 542/95 as amended. The MAH applied for a variation to demonstrate compliance with Commission Directive 1999/82/EC and the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products (CPMP/BWP/1230/98 rev.1) and provided scientific information, which was then supplemented by a Certificate of Suitability issued by the European Pharmacopoeia. The procedure started on 17 November 2000 and supplementary information was provided on 26 February 2001. The CPMP adopted a positive Opinion for this variation on 29 March 2001 and did not require any amendment to the Community Marketing Authorisation.
- Pursuant to article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the MAH notified the EMEA on 22 March 2001 of their intention to introduce changes to an aspect of the PL not connected to the SPC. On 25 April 2001, the EMEA notified the European Commission that the changes were accepted. Amendments to the Annex IIIB of the Community Marketing Authorisation were required and the Commission Decision was issued on 20 June 2001.
- On 10 August 2001 the MAH submitted to the EMEA an application for a Type I variation in accordance with Article 4 of European Commission Regulation (EC) No. 542/95, as amended. The scope of this variation was to extend the shelf life as foreseen at time of authorisation from 2 years to 3 years. The procedure started on 30 August 2001. The EMEA notified the European Commission on 28 September 2001 that the variation was accepted. Amendments to the Annexes I and IIIB of the Community Marketing Authorisation were required and the Commission Decision was issued on 21 November 2001.

- Pursuant to article 61(3) of Council Directive No. 2001/83/EC of 6 November 2001, the MAH notified the EMEA on 4 October 2001 of their intention to introduce changes to an aspect of the PL not connected to the SPC. On 19 November 2001, the EMEA notified the European Commission that the changes were accepted. Amendments to the Annex III of the Community Marketing Authorisation were required and the Commission Decision was issued on 28 January 2002.
- On 11 April 2002 the MAH submitted an application for a Type II variation in accordance with Article 6 of Commission Regulation (EC) 542/95 as amended. The MAH applied for an update of the SPC sections 4.2, 4.3, 4.4, 4.6 and 4.8 in order to reflect changes to the MAH's reference safety information (Core Data Sheet) and increase international labelling consistency. The procedure started on 26 April 2002. The CPMP adopted a positive Opinion for this variation on 27 June 2002. The respective Commission Decision was issued on 10 September 2002.
- Pursuant to article 61(3) of Council Directive No. 2001/83/EC of 6 November 2001, the MAH notified the EMEA on 3 February 2003 of their intention to introduce changes to an aspect of the PL not connected to the SPC. On 17 February 2003, the EMEA notified the European Commission that the changes were accepted. Amendments to the Annex III of the Community Marketing Authorisation were required and the Commission Decision was issued on 17 March 2003.
- On 12 March 2003 the MAH submitted an application for a Type II variation in accordance with Article 6 of Commission Regulation (EC) 542/95 as amended. The MAH applied for an update of the section 4.8 the SPC in order to include information on anaphylactic reactions and section 4.4 to reword the sentence on psycho-motor coordination. The corresponding sections of the PL were also amended. The procedure started on 21 March 2003. The CPMP adopted a positive Opinion for this variation on 22 May 2003. The respective Commission Decision was issued on 16 September 2003.