PROCEDURAL STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the MAH notified the EMEA on 17 May 1999 of their intention to introduce changes to an aspect of the Package Leaflet not connected to the Summary of Product Characteristics (EMEA/H/C/233/N/01). The MAH applied to correct errors in the local representative addresses in all languages. The EMEA notified the European Commission that the above mentioned changes were acceptable on 7 July 1999.
- Pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, the MAH submitted to the EMEA on 22 July 1999 an application for a Type I variation (EMEA/H/C/233/I/02). The MAH applied for a change of the manufacturing site for part of the manufacturing process. The EMEA notified the European Commission that the above mentioned variation was acceptable on 23 August 1999.
- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the MAH notified the EMEA on 25 January 2000 of their intention to introduce changes to an aspect of the Package Leaflet not connected to the Summary of Product Characteristics (EMEA/H/C/233/N/03). The MAH applied to correct changes in the local representatives in some Member States. The EMEA notified the European Commission that the above mentioned changes were acceptable on 14 February 2000.
- Pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, the MAH submitted to the EMEA on 15 November 2000 an application for a Type I variation (EMEA/H/C/233/I/05). The MAH applied to add an alternative manufacturing site for the final step of the synthesis of the active substance. The EMEA notified the European Commission that the above mentioned variation was acceptable on 19 December 2000.
- Pursuant to Article 3 of Commission Regulation (EC) No 2141/96 of 7 November 1996, ASTA Medica Aktiengesellschaft, Germany, submitted to the EMEA on 18 December 2000 an application for the transfer of the Marketing Authorisation for Cetrotide to Ares-Serono (Europe) Ltd, United Kingdom (EMEA/H/C/233/T/06). The EMEA notified the European Commission that the above mentioned transfer was acceptable on 16 January 2001. On 20 March 2001, the Commission Decision was given for a transfer of Marketing Authorisation to Ares-Serono (Europe) Ltd.
- On 12 January 2001, the MAH applied for a Type II variation procedure related to the update of the Summary of Product Characteristics and Package Leaflet to include new safety information, particularly further to the evaluation of the 3rd Periodic Safety Update Report (EMEA/H/C/233/II/07). On 31 May 2001, the CPMP adopted an Opinion on this variation and the respective Commission Decision was issued on 20 September 2001.
- Pursuant to Article 6 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, the MAH submitted to the EMEA on 15 January 2001 an application for a Type II variation (EMEA/H/C/233/II/08). The MAH applied for a variation to change the end of shelf life peptide purity specifications for Cetrotide 0.25 mg, and requested a widening of the limits for the degradation product. On 29 March 2001, the CPMP adopted an Opinion on this variation and agreed on the commitment by the MAH to provide 24 months stability data as a follow up measure. The respective Commission Decision was issued on 2 May 2001.
- Pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, the MAH submitted to the EMEA on 8 February 2002 an application for a Type I variation (EMEA/H/C/233/I/09). The MAH applied for a change of the name of the manufacturer. The EMEA notified the European Commission that the above mentioned variation was acceptable on 15 March 2002.

- Pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, the MAH submitted to the EMEA on 8 February 2002 an application for a Type I variation (EMEA/H/C/233/I/10). The MAH applied for a change of the name and address of the Marketing Authorisation Holder. The EMEA notified the European Commission that the above mentioned variation was acceptable on 15 March 2002.
- Pursuant to Article 6 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended, Serono Europe Limited submitted to the EMEA on 18 July 2002 an application for a Type II variation (EMEA/H/C/233/II/11). This variation relates to an update of the Summary of Product Characteristics following the evaluation of the 4th Periodic Safety Update Report with respect to the first injection of Cetrotide and pseudo-allergic/allergic reactions. On 17 October 2002, the CPMP adopted an Opinion on this variation. The respective Commission Decision was issued on 15 January 2003.
- Pursuant to Article 61(3) of Directive 2001/83/EC, the MAH notified the EMEA on 18 December 2002 of their intention to introduce changes to an aspect of the Package Leaflet not connected to the Summary of Product Characteristics (EMEA/H/C/233/N/12). The MAH applied to change the contact details of the local representatives in all languages. The EMEA notified the European Commission that the above mentioned changes were acceptable on 10 February 2003.