PROCEDURAL STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- On 13 July 2001, the EMEA issued a notification for the following type I variation: extension of the shelf-life of the active substance.
- On 13 July 2001, the EMEA issued a notification for the following type I variation: extension of the shelf-life of the finished product.
- On 31 July 2001, the EMEA issued an opinion on a transfer of the marketing authorisation to Dompé Biotec S.p.A. The Commission Decision amending the Community Marketing Authorisation was adopted on 1 October 2001.

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Additional indication	II/4	II	28.05.02	22.08.02
Change in the name of a manufacturer of the medicinal product	I/5	I	11.04.02	16.05.02
Change in test procedure of active substance	I/6	I	11.04.02	16.05.02
Change in test procedure for starting material/intermediate used in manufacturing of active substance	I/7	I	11.04.02	16.05.02
Change in test procedure of active substance	I/8	I	29.05.02	31.05.02
Change in manufacture of active substance	I/9	I	27.06.02	30.07.02
Minor change of manufacturing process	I/10	I	27.06.02	10.07.02
Batch size of active substance	I/11	I	27.06.02	10.07.02
Change in test procedure of medicinal product	I/12	I	21.06.02	10.07.02
Change in the address of the MAH	I/13	I	30.08.02	11.10.02
Update of Summary of Product Characteristics and Package Leaflet	II/15	II	21.11.02	27.02.03
Extension of Indication	II/16	II	22.05.03	11.08.03
Change in the batch size of finished product	I/17	I	19.03.03	02.04.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/18	I	10.04.03	24.04.03
Change in specification of starting material/intermediate used in manuf. of the active substance	I/19	I	03.04.03	08.04.03
Update of or change(s) to the pharmaceutical documentation and Change(s) to the test method(s) and/or specifications for the finished product	II/20	II	24.07.03	28.07.03

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.