STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 31 July 2004 please refer to module 8B.

- The MAH submitted on 22 April 1999, an application for a Notification of a Type I Variation No 1 of Annex I, in order to apply for a change in the name of the manufacturer of the medicinal product, pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended. The procedure started on 29 April 1999. A positive Notification was signed by the Head of Human Unit at the EMEA on 25 May 1999 and forwarded to the European Commission, which adopted a decision on 29 July 1999. (EMEA/H/C/206/I/01)
- The MAH submitted on 22 April 1999, an application for a Notification of a Type I Variation No 11 of Annex I, in order to apply for a change in the name of the manufacturer of the active substance, pursuant to Article 4 of Commission Regulation (EC) No 542/95 of 10 March 1995, as amended. The procedure started on 29 April 1999. A positive Notification was signed by the Head of Human Unit at the EMEA on 25 May 1999 and forwarded to the European Commission, which adopted a decision on 29 July 1999. (EMEA/H/C/206/I/02)
- The MAH submitted on 22 April 1999 a Notification to the EMEA in order to introduce changes to the Package Leaflet not connected to the Summary of Product Characteristics, pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992. The procedure started on 29 April 1999. The Notification was signed by the Head of Human Medicines Evaluation Unit on 25 May 1999 and forwarded to the European Commission, which adopted a decision on 29 July 1999 (EMEA/H/C/206/N/03).

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
Minor change in the manufacturing process of the active ingredient	I/04	I/II	16.11.00	
Update of Summary of Product Literature and leaflet	II/05	II	23.08.01	28.01.02
Change(s) to the test method(s) and/or specifications for the active substance & Change(s) to the test method(s) and/or specifications for the finished product	II/06	II	23.01.03	28.01.03
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/07	N	15.11.02	16.12.02
Update of Summary of Product Characteristics and Package Leaflet	II/08	II	25.09.03	27.01.04
Update of or change(s) to the pharmaceutical documentation	II/09	II	17.12.03	23.12.03
Renewal	R/10	R	26.02.04	17.06.04

[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.