STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- On 12 November 1999 the Marketing Authorisation Holder submitted an application for a Type I variation in accordance with Commission Regulation (EC) No. 542/95 relating to a change in the address of the Marketing Authorisation Holder. The EMEA approved the variation on 9 December 1999, which required amendments to be incorporated in the relevant sections of the Commission Decision. The European Commission amended the Decision on 22 February 2000.

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 labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/02	N	05.10.00	01.12.00
Change in the name of a manufacturer of the active substance	I/03	I	15.11.00	N/A
Extension of shelf-life or retest period of the active substance	I/04	I	16.11.00	N/A
1ST Annual reassessment	S/05	S	16.11.00	--
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/06	N	24.01.01	06.03.01
Quality changes; PhEur certificate of suitability related to TSE issues.	II/08	II	25.04.01	N/A
Annual reassessment	S/09	S	13.12.01	12.04.02
Batch size of active substance	I/10	I	21.06.02	28.06.02
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/11	I	25.03.03	31.03.03
Change in the name and/or address of the marketing authorisation holder	I/12	I	04.03.03	10.04.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/13	I	16.04.03	28.04.03
Change in container shape	I/14	I	16.04.03	28.04.03
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/15	N	11.04.03	12.05.03
Update of Summary of Product Characteristics and Package Leaflet	II/16	II	26.06.03	03.10.03
Extension of Indication and Update of Summary of Product Characteristics and Package Leaflet	II/17	II	24.03.04	07.05.04
Change in supplier of packaging components - replacement/addition	IB/18	IB	03.02.04	-
Change in qual./quant. composition of immediate packaging - all other pharm. forms	IA/19	IA	28.01.04	-
Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	IA/20	IA	28.01.04	-
Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec and Change in the specification of the finished product - tightening of specification limits	IA/21	IA	10.03.04	-
Replacement/add. of manufacturing site: Secondary packaging site	IA/24	IA	30.03.04	-
Change in BR/QC testing - repl./add. of batch control/testing site	IA/25	IA	30.03.04	-

[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.