STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedure finalised after 1 January 2005 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Transfer of Marketing Authorisation Holder	T/001	T	11.12.01	19.02.02
Change in the manufacturing authorisation	I/002	I	25.01.02	12.04.02
Change in the name of a manufacturer of the active substance	I/003	I	17.01.02	06.03.02
Transfer of Marketing Authorisation Holder	T/004	T	06.08.02	13.09.02
Change in the manufacturing authrisation	I/005	I	11.11.02	05.12.02
Change in the name of the manufacturer of active substance	I/006	I	06.11.02	12.11.02
1st annual reassessment of benefit/risk profile	S/007	S	19.03.03	09.07.03
Extension of retest period of active substance	I/008	I	15.08.03	20.08.03
Extension of shelf-life of finished product	I/009	I	09.09.03	20.10.03
2nd annual reassessment of benefit/risk profile	S/010	S	20.11.03	20.02.04

[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.