STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 August 2003 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/01	T	28.10.02	04.12.02
Change in or addition of manufacturer(s) of active substance	I/02	I	04.03.03	11.03.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/03	I	07.04.03	10.04.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/04	I	14.03.03	22.04.03
Change in the name of the medicinal product (either invented name of common name)	I/05	I	14.03.03	22.04.03
Change of imprints/bossing/marking on tablets/printing on capsules, incl. addition/change of inks	I/06	I	14.03.03	22.04.03
Change in the name of a manufacturer of the medicinal product and Change in the name of a manufacturer of the active substance	I/07	I	20.05.03	28.05.03
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/08	I	20.06.03	25.06.03
Change in specification of starting material/intermediate used in manuf. of the active substance	I/09	I	20.06.03	26.06.03
Change in specifications of active substance and Change in test procedure of active substance	I/10	I	17.07.03	24.07.03
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/11	I	04.07.03	09.07.03
Change in or addition of manufacturer(s) of active substance	I/12	I	18.07.03	25.07.03

[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.