STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 4 June 2003 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of the indication	II/01	II	25.04.02	19.07.02
Addistion of a new pharmaceutical form	X/02	Extension	16.12.02	16.04.03
Update of SPC and Package Leaflet	II/03	II	20.02.03	04.06.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/04	I	13.12.02	07.01.03
Changes to the the test methods and specifications for the active substance	II/06	II	25.04.03	30.04.03

[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.