STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 June 2002 please refer to module 8B.

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 of manufacturing process of the active substance	I/01	I	20.09.01	08.10.01
Quality changes	II/02	II	15.11.01	28.11.01
Quality changes	II/03	II	20.09.01	08.10.01
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/04	I	26.10.01	-
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/05	I	21.12.01	21.01.02
Minor changes in manufacture of the medicinal product	I/06	I	30.05.02	07.06.02
Change in test procedures of the medicinal product	I/07	I	25.04.02	06.05.02
Minor change in package leaflet not connected with the SPC (Art. 61(3) Notification)	N/08	N	15.03.02	18.04.02
Change in test procedure for starting material/intermediate used in manuf. of active substance	I/09	I	15.03.02	19.03.02

[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.