Procedural steps taken after granting the Marketing Authorisation

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change in the name and/or address of the marketing authorisation holder	I/01	I	04.04.03	12.05.03
Change in test procedures of the medicinal product	I/02	I	08.05.03	14.05.03
Change in test procedure of active substance and Change in test procedures of the medicinal product and Change in test procedure for starting material/intermediate used in manuf. of active substance	I/03	I	24.07.03	05.08.03
Update of or change(s) to the pharmaceutical documentation	II/05	II	21.01.04	26.01.04

[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.