Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 October 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
Clinical changes (additional primary dose schedule)	II/0001	II	27.06.01	24.10.01
Change in container shape	I/0003	I	27.06.01	-
Changes to comply with supplements to pharmacopoeias	I/0004	I	27.06.01	-
Change in specifications of active substance	I/0005	I	27.06.01	-
Quality changes	II/0006	II	20.09.01	23.10.01
Quality change Minor change of manufacturing process of the active substance	I/0007	I	27.06.02	-
Quality change : Minor change of manufacturing process of the active substance	I/0008	I	27.06.02	-
Quality change: Quality: Update of or change(s) to the pharmaceutical documentation	II/0009	II	27.06.02	02.07.02
Quality change Change(s) to the test method(s) and/or specifications for the active substance and the finished product	II/0010	II	25.04.02	06.05.02
Quality change: Change to comply with supplements to pharmacopoeias.	I/0011	I	12.04.02	-
Quality change: Change in supplier of an intermediate compound used in manufacture of the active substance.	I/0012	I	09.07.02	-

[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.