Steps taken after granting the Marketing Authorisation

For procedures finalised after 01/11/04 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of shelf-life or retest period of the active substance	I/03	I	02.12.02	11.12.02
Update of Summary of Product Characteristics and Package Leaflet	II/04	II	24.07.03	07.11.03
Addition of new strength	X/05	X	24.07.03	24.10.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/06	I	07.08.03	22.09.03
Extension of Indication and Addition of new strength	X/07	X	29.07.04	12.11.04
Minor change in the manufacturing process of the active substance and Change in spec. of active subst./agent used in manuf. of active subst. – tightening	IB/08	IB	13.01.04	-
Change in the specification of the finished product - tightening of specification limits	IB/09	IB	13.01.04	-
Change in test procedure of finished product - other changes	IB/11	IB	21.07.04	-

[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.