Steps taken after granting the Marketing Authorisation

For procedures finalised after 01 November 2002 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change in batch size of active substance	I/II0001	I/II	25.01.01	22.11.01
Quality change (demonstration of TSE compliance)	II/0002	II	15.11.01	-
Changes to comply with supplements to pharmacopoeias	I/0003	I	23.03.01	22.11.01
Change in test procedures of the medicinal product	I/II/0004	I/II	26.04.01	-
Extension of shelf-life as foreseen at time of authorisation	I/0005	I	26.03.01	16.07.01
Change(s) to the test method(s) and/or specifications for the active substance	II/0006	II	23.08.01	24.09.01
Quality changes	II/0007	II	20.09.01	02.10.01
Change in name of manufacturing site	I/0008	I	16.11.01	-
Change in the name of MAH and manufacturer responsible for batch release	I/0009	I	05.11.01	-
Change in pack size for a medicinal product	I/0010	I	07.11.01	-
Change in pack size for a medicinal product	I/0011	I	07.11.01	-
Change in name of manufacturing site	I/0012	I	16.11.01	-
Change(s) to the test method(s) and/or specifications for the finished product	II/0013	II	30.05.02	07.06.02
Change in container shape	I/0014	I	20.09.02	27.09.02
Changes to the Patient Leaflet regarding some MAH local representative details	N/0015	N	19.09.02	08.10.02

[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.