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
Batch size of active substance	I/II/0001	I/II	25.01.01	22.11.01
Change in container shape	I/0002	I	22.01.01	22.11.01
Quality change (demonstration of TSE compliance)	II/0003	II	15.11.01	
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/0004	I	14.03.01	22.11.01
Changes to comply with supplements to pharmacopoeias	I/0005	I	23.03.01	22.11.01
Change in test procedures of the medicinal product	I/II/0006	I/II	26.04.01	
Extension of shelf-life as foreseen at time of authorisation	I/0007	I	26.03.01	16.07.01
Extension of shelf-life as foreseen at time of authorisation	I/0008	I	14.06.01	22.11.01
Change(s) to the test method(s) and/or specifications for the active substance	II/0009	II	23.08.01	24.09.01
Quality change	II/0010	II	20.09.01	
Change in the name of a manufacturer of the medicinal product	I/0011	I	05.11.01	
Change of name of MAH and manufacturer for batch release	I/0012	I	05.11.01	
Change in the pack size for a medicinal product	I/0013	I	07.11.01	
Change in the pack size for a medicinal product	I/0014	I	07.11.01	
Change in the name of the MAH and manufacturer responsible for batch release	I/0015	I	16.11.01	
Quality: Change(s) to the test method(s) and/or specifications for the finished product	II/0016	II	30.05.02	07.06.02
Update of the Summary of Product Characteristics section 4.8 (Undesirable effects) and Package Leaflet (PL) to incorporate new safety information and minor changes on new details of some MAH local representatives.	II/0017	II	25.07.02	24.10.02
Quality: Change(s) to the test method(s) and/or specifications for the finished product Quality: Change(s) to the test method(s) and/or specifications for the active substance	II/0018	II	17.10.02	30.10.02
Change in container shape	I/0019	II	20.09.02	27.09.02

[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.