Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 October 2003 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/amen-ded on
61(3) Notification to update the contact details of local representatives	N/0001	N	06.09.02	08.10.02
Minor change of manufacturing process of the active substance	I/0002	I	03.10.02	N/A
Change in test procedure of active substance	I/0003	I	03.10.02	N/A
Change in test procedures of the medicinal product	I/0004	I	03.10.02	N/A
Change in the address of the marketing authorisation holder	I/0005	I	03.10.02	07.11.02
Addition of 10 g packsize for Protopy 0.03% and 0.1%.	I/0006	I	20.02.03	10.04.03
Extension of shelf-life as foreseen at time of authorisation	I/0007	I	01.08.03	22.09.03

[1] For variations before 1 October 2003 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 61(3) of Council Directive 2001/83/EC 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.