Steps taken after granting the Marketing Authorisation

For procedures finalised after 1 October 2004 please refer to module 8B.

- On 03 August 1999 the Marketing Authorisation Holder submitted to the EMEA six applications for Type I variations in accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. These variations were related to a change in the batch size of the active substance, minor changes of the manufacturing process of the active substance and changes in the specifications of the active substance. The variations were approved by the EMEA on 07 September 1999 and did not require any amendments to the Commission Decision.

- On 22 May 2000 the Marketing Authorisation Holder submitted to the EMEA four applications for Type I variations in accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. These variations were related to a change in the batch size of the finished product (with consequential minor changes in the manufacture of the medicinal product), minor changes of the manufacture of the medicinal product and changes in the test procedure of the active substance. The variations were approved by the EMEA on 27 June 2000 and did not require any amendments to the Commission Decision.

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
Alternate manufacturer	II/0012	II	17.01.02	07.02.02
Change in test procedure of active substance (three separate tests)	I/0013 - 15	I	09.08.01	--
Change in finish product specification	II/0016	II	18.10.01	17.12.01
Update of the SPC (point 4.4, 4.8)	II/0017	II	13.12.01	19.04.02
Update of the SPC (point 4.8, 5.1)	II/0018	II	27.06.02	03.10.02
Minor change in manufacture of medicinal product	I/0019	I	12.08.02	05.09.02
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0021	N	13.02.03	24.03.03
Minor change of manufacturing process of the active substance	I/0022	I	15.04.03	28.04.03
Extension of shelf-life or retest period of the active substance	I/0023	I	10.09.03	18.09.03
Update of Summary of Product Characteristics and Package Leaflet	II/0024	II	17.12.03	23.02.04
Renewal	R/0025	R	23.06.04	02.09.04
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0027	N	19.05.04	-

[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.