

## STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

Scope	Application number	Type of modification <sup>1</sup>	Notification/Opinion issued on <sup>2</sup>	Commission Decision Issued/amended on
Change in the name and/or address of the marketing authorisation holder	I/001	I	18.03.02	29.04.02
Minor change in labelling or package leaflet not connected with the SPC (Art. Notification 61(3))	N/002	N	09.10.02	11.10.02
Annual Re-assessment	S/003	S	19.09.02	18.12.02
Minor change in labelling or package leaflet not connected with the SPC (Art. Notification 61(3))	N/004	N	21.02.03	08.04.03
Minor change of manufacturing process of the active substance	I/005	I	25.04.03	02.05.03
Minor change of manufacturing process of the active substance	I/006	I	23.01.03	27.01.03
Update of Summary of Product Characteristics	II/007	II	19.03.03	25.06.03
Change in specification of the medicinal product	I/008	I	12.03.03	13.03.03
Change in the name of a manufacturer of the active substance	I/009	I	12.03.03	13.03.03
Update of Summary of Product Characteristics	II/010	II	21.08.03	04.12.03
Update of Summary of Product Characteristics and Package Leaflet	II/011	II	22.10.03	20.01.04
Annual reassessment	S/012	S	25.09.03	09.01.04
Change or addition of a new strength/potency	X/013	X	29.07.04	29.10.04

<sup>1</sup> 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.

<sup>2</sup> 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.