

## STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 30 June 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 address of the MAH	I/02	I	11.06.02	10.07.02
Change in the manufacturing and filling site of the finished product	I/04	I	04.02.03	--
Change in the batch size of the finished product	I/05	I	04.02.03	--
Minor change in the manufacturing process of the finished product	I/06	I	04.02.03	--
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/07	N	13.02.03	10.04.03
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/08	N	15.05.03	11.06.03
Change in the name and address of a manufacturer of the finished product	IA/09	IA	23.03.04	--

<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.