

## Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 October 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
Addition of manufacturer and change of manufacturing process of the active substance	II/0001	II	27.06.01	04.07.01
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0002	N	13.12.01	19.02.02
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0003	N	18.03.02	29.04.02
Update of Summary of Product Characteristics (section 4.8) and Package Leaflet following the assessment of the 1 <sup>st</sup> and 2 <sup>nd</sup> PSURs.	II/0004	II	19.09.02	04.12.02
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0005	N	03.03.03	24.03.03
Urgent Safety Restriction	-	-	19.05.04	-
Update of Summary of Product Characteristics and Package Leaflet following the Urgent Safety Restriction	II/0007	II	29.07.04	27.09.04

<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.