STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of Indication	II/02	II	20.05.99	18.08.99
Update of or change(s) to the pharmaceutical documentation	II/04	II	21.03.02	11.04.02
Change in test procedure of active substance	I/05	I	16.03.01	-
Change in specifications of active substance	I/06	I	18.04.01	-
Update of Summary of Product Characteristics and Package Leaflet	II/07	II	15.11.01	11.04.02
Change in in-process controls applied during the manufacture of the product	I/08	I	30.08.02	04.09.02
Update of Summary of Product Characteristics and Package Leaflet	II/09	II	21.11.02	06.03.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/10	I	17.01.03	22.01.03
Minor changes in manufacture of the medicinal product	I/11	I	15.08.03	21.08.03
Renewal	R/13	R	20.11.03	10.03.04
Update of Summary of Product Characteristics and Package Leaflet	II/14	II	20.11.03	05.02.04
Replacement/add. of manufacturing site: Primary packaging site - Solid forms	IA/15	IA	09.12.03	-
Replacement/add. of manufacturing site: Primary packaging site - Solid forms	IA/16	IA	23.01.04	-
Change in BR/QC testing - repl./add. of batch control/testing site	IA/17	IA	23.01.04	-
Change in BR/QC testing - repl./add. of batch control/testing site	IA/18	IA	23.01.04	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/19	N	07.05.04	-

[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.