

STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 April 2005 please refer to module 8B.

Scope	Application number	Type of modification ¹	Notification/Opinion issued on ²	Commission Decision Issued/amended on
Update of Summary of Product Characteristics and Package Leaflet	II/01	II	25.04.03	23.07.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/02	I	26.11.02	14.01.03
Withdrawal of the manufacturing authorisation for a site of manufacture	I/03	I	26.11.02	14.01.03
Change in container shape	I/04	I	19.12.02	
Change(s) to the test method(s) and/or specifications for the active substance	II/05	II	24.04.03	02.05.03
Update of or change(s) to the pharmaceutical documentation	II/06	II	22.10.03	14.01.04
Extension of Indication	II/07	II	16.09.04	29.10.04
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/08	N	11.05.04	-
Extension of Indication	II/09	II	15.12.04	26.01.05
Change in pack size - change in no. of units outside range of appr. pack size	IB/10	IB	21.07.04	-
Extension of Indication	II/11	II	20.01.05	23.02.05
Change in shelf-life of finished product - as packaged for sale	IB/12	IB	11.01.05	-
Change in test procedure of finished product - minor change to approved test procedure	IA/13	IA	11.02.05	-
Change in test procedure of finished product - minor change, biol. active subst./excipient	IB/16	IB	02.03.05	-
Add/replacement/del. of measuring or administration device - addition or replacement	IA/17	IA	24.02.05	-

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.