

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 ¹	Notification/Opinion issued on ²	Commission Decision Issued/amended on
Minor change of manufacturing process of the active substance	I/0001	I	21.07.03	-
Change (s) to the manufacturing process for the finalised product. Change(s) to the test method(s) and/or specifications for the active substance.	II/0002	II	24.03.04	31.03.04
Change in test procedure of finished product – minor change to approved test procedure.	IA/0003	IA	27.01.04	-
Add/ replacement/ del. Of measuring or administration device – addition or replacement.	IA/0004	IA	02.02.04	-
Update of the Summary of Product characteristics (SPC) and package Leaflet (PL).	II/0005	II	22.04.04	08.06.04
Annual Re-assessment.	S/0006	S	29.07.04	15.10.04
Change in the name and/or address of a manufacturer of the finished product.	IA/0007	IA	21.09.04	21.09.04

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.