

STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 30 November 2004 please refer to module 8B

Scope	Application number	Type of modification ¹	Notification/Opinion issued on ²	Commission Decision Issued/amended on
Change in the name and/or address of the marketing authorisation holder	I-001	I	11.04.02	17.05.02
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I-002	I	18.09.02	24.09.02
Annual reassessment	S-003	S	26.06.03	08.10.03
Change in the name and/or address of a manufacturer of the finished product	IA-004	IA	07.01.04	-
Change in shelf-life of finished product - as packaged for sale	IB-005	IB	04.02.04	-
Change in the name and/or address of a manufacturer of the finished product	IA-006	IA	23.02.04	-
Change in the specification of the finished product - tightening of specification limits	IA-007	IA	09.03.04	-
Change in re-test period of the active substance	IB-008	IB	24.03.04	-
Change in BR/QC testing - repl./add. of batch control/testing site	IA-009	IA	10.03.04	-
Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	IA-010	IA	10.03.04	-
Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec.	IA-011	IA	09.03.04	-
Quality changes	II-12	II	18.11.04	24.11.04
Annual reassessment	S-013	S	03.06.04	09.09.04

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.