STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 November 2004 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	II/001	II	18.12.02	20.03.03
Extension of shelf life for the finished product	I/002	I	02.12.02	15.01.03
Extension of the retest period for the active substance	I/003	I	02.12.02	11.12.02
Update of Summary of Product Characteristics and Package Leaflet	II/004	II	24.07.03	07.11.03
Addition of new strength	X/005	X	24.07.03	24.10.03
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/006	I	07.08.03	22.09.03
Minor change in the manufacturing process of the active substance and Change in spec. of active subst./agent used in manuf. of active subst. - tightening	IB/008	IB	13.01.04	-
Change in the specification of the finished product - tightening of specification limits	IB/009	IB	13.01.04	-
Change in test procedure of finished product - other changes	IB/011	IB	21.07.04	-

Medicinal Product no longer authorised

[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.

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