Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 February 2004 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Transfer of Marketing Authorisation Holder	T/01	T	20.12.02	27.01.03
Update of or change(s) to the pharmaceutical documentation and Change(s) to the manufacturing process for the active substance	II/02	II	22.05.03	02.06.03
Update of Summary of Product Characteristics and Package Leaflet	II/03	II	20.11.03	29.01.04
Update of or change(s) to the pharmaceutical documentation	II/04	II	17.12.03	15.01.04

[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.