**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 |
|---|---|---|---|---|
| Update of or change(s) to the pharmaceutical documentation and Change(s) to the manufacturing process for the active substance | II/01 | II | 22.05.03 | 02.06.03 |
| Update of Summary of Product Characteristics and Package Leaflet | II/02 | II | 20.11.03 | 29.01.04 |
| Change(s) to the manufacturing process for the active substance | II/03 | II | 17.12.03 | 15.01.04 |
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[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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