## STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 01/08//2004, please refer to module 8B

| Scope | Application number | Type of modification[1] | Notification/ Opinion issued on[2] | Commission Decision Issued/amended on |
|---|---|---|---|---|
| The Marketing Authorisation Holder (MAH) applied to update sections 4.8 (Undesirable effects) and 5.1 (Pharmacodynamic properties) of the Summary of Product Characteristics (SPC) to include 48-week safety and efficacy data available from clinical study 045. The labelling has been updated to bring storage declarations in line with current guidelines. In the Package Leaflet (PL), the list of local representatives has been updated to include the 10 new EU Member States. | II-01 | II | 03.06.2004 | 19.07.2004 |
| The MAH applied for a Notification in order to include the additional local representatives of the MAH for all 10 new European Member States and to present the list according to the latest version of the EMEA QRD templates. The MAH took this opportunity to also update the storage conditions in all the languages according to the new 3rd Appendix to the EMEA QRD Templates for Human Medicinal Products and to make some linguistic improvements. | N-02 | N | 20.05.2004 | - |

[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.