

## Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 April 2003, please refer to module 8B.

- On 25 November 1998 three Type I variation procedures were started to introduce minor changes to the manufacture of the active substance (I/01) and to the finished product (I/02-03). The proposed variations were accepted on 23 December 1998.
- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the Marketing Authorisation Holder notified the EMEA on 27 June 2000 of their intention to introduce changes to aspects of the package leaflet not connected to the Summary of Product Characteristics (changes in contact details of local representatives in the Package Leaflet). The EMEA approved this Notification on 16 August 2000. The Commission Decision was issued on 9 October 2000.

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

Scope	Application number	Type of modification <sup>1</sup>	Notification/ Opinion issued on <sup>2</sup>	Commission Decision Issued/amended on
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/05	N	31.01.01	13.03.01
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/06	N	23.10.01	17.12.01
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/07	N	15.03.02	19.04.02
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/08	N	07.06.02	27.06.02
Renewal	R/09	R	18.12.02	17.03.03

<sup>1</sup> 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.

<sup>2</sup> 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.