STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation that referred to the addition of an alternative packaging site. A notification was issued on 12 October 2000.
- The Manufacturing Authorisation Holder (MAH), in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type II variation procedure regarding the update of the Plasma Master File. A positive opinion was adopted by the CPMP on 19 October 2000.

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

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Quality changes Alternative fermenter size	II/01	II	16.11.00	23.11.00
Update of or change(s) to the pharmaceutical documentation	II/04	II	30.05.02	05.06.02
Change in storage conditions	I/06	I	13.08.01	24.10.01
Quality changes	II/07	II	13.12.01	17.12.01
Minor changes in manufacture of the medicinal product and Change in the batch size of finished product	I/08	I	25.04.02	30.04.02
Update of Summary of Product Characteristics and Package Leaflet	II/09	II	19.09.02	05.12.02
Change(s) to the test method(s) and/or specifications for the active substance	II/10	II	19.09.02	25.09.02
Quality changes	II/11	II	17.10.02	23.10.02
Change in or addition of manufacturing site(s) for part or all of the manufacturing process	I/12	I	13.12.02	31.01.03

[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.