

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/0001	II	16.11.00	23.11.00
Alternative packaging site	I/0003	I	12.10.00	20.12.00
Demonstration of TSE compliance	II/0004	II	28.05.02	05.06.02
Change in storage conditions	I/0006	I	13.08.01	24.10.01
Plasma Master File Update	II/0007	II	13.12.01	17.12.01
Change of batch size and freeze-drying cycle	I/0008	I	24.04.02	30.04.02
Update of the SPC (point 4.8) following 2nd PSUR	II/0009	II	19.09.02	05.12.02
Change in specifications and action limits for In-process controls	II/0010	II	19.09.02	25.09.02
Plasma master file update 2002	II/0011	II	17.10.02	23.10.02

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.