

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 |
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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.