Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 September 2000 please refer to module 8B.

- The Marketing Authorisation Holder (MAH), in accordance with Commission Regulation (EC) No. 542/95 submitted an application for a Type I variation to change the name of the manufacturer of the finished medicinal product from Sanofi Winthrop, Inc., USA to Abbott Laboratories, USA. The variation was accepted on 22 April 1998.
- The MAH, in accordance with Commission Regulation (EC) No. 542/95 submitted an application for a Type II variation which referred to the optimisation of the lyophilisation cycle, which was withdrawn on 8 July 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type II variation to amend the text of the SPC, labelling and Package Leaflet in the light of the data in the first PSUR. The proposed texts included revised information on posology, pharmacokinetics and adverse reactions, including cases of severe anaphylaxis. A positive opinion was adopted by the CPMP on 23 July 1998. The Commission decision amending the marketing authorisation was adopted on 11 November 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the specification of the medicinal product; a notification was issued on 8 December 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the specification of the medicinal product; a notification was issued on 8 December 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the specification of the active substance; a notification was issued on 8 December 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the specification of the active substance; a notification was issued on 9 October 1998.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the address of the Marketing Authorisation Holder; and a notification was issued on 26 October 1998. The Commission Decision amending the Marketing Authorisation was adopted on 11 January 1999.
- Persuant to Article 13(2) of Council regulation (EC) No. 2309/93, as amended, the Marketing Authorisation Holder submitted to the EMEA on 27 August 1998, the documentation that formed the basis of the first annual re-assessment of the benefit/risk profile for BeneFIX. A positive opinion was issued on 19 November 1998. The Commission Decision amending the Marketing Authorisation was adopted on 29 March 1999.
- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC, the Marketing Authorisation Holder notified the EMEA of a change of address of the Greek representative; a notification was issued on 22 February 1999. The Commission Decision amending the Marketing Authorisation was adopted on 8 April 1999.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in the specification of the active substance; a notification was issued on 30 June 1999.
- The MAH in accordance with Commission Regulation (EC) No. 542/95, as amended, submitted an application for a Type I variation which referred to a change in specification of the finished product; a notification was issued on 30 June 1999.
- Persuant to Article 13(2) of Council regulation (EC) No. 2309/93, as amended, the Marketing Authorisation Holder submitted to the EMEA on 2 September 1999, the documentation that

formed the basis of the second annual re-assessment of the benefix/risk profile for BeneFIX. A positive opinion was issued on 18 November 1999. The Commission Decision amending the Marketing Authorisation was adopted in March 2000.