Procedural steps taken after granting the Marketing Authorisation

For procedures finalised after 1 May 2002 please refer to module 8B.

- The Marketing Authorisation Holder submitted to the EMEA on 29 January 2001 an application for a type I variation falling within the scope of item No. 24 (change of the method for the assay and identification of acetate in ganirelix drug substance) of Annex I to Commission Regulation (EC) No 542/95. On 7 March 2001, the EMEA approved the variation (EMEA/H/C/274/I/01). This variation did not require amendments to the Commission Decision.
- The Marketing Authorisation Holder submitted to the EMEA on 28 June 2001 an application for one type I variation falling within the scope of item No 20 of Annex I to Commission Regulation (EC) No 542/95. The Marketing Authorisation Holder applied for an extension of shelf life as foreseen at the time of authorisation from 18 months to 2 years. On 16 July 2001, the EMEA approved the variation (EMEA/H/C/274/I/02). This variation required amendments to annex I of the Community Marketing Authorisation. The respective Commission Decision was issued on 18 September 2001.
- The Marketing Authorisation Holder submitted to the EMEA on 17 October 2001 an application for a type II variation in accordance with Article 6 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. The scope of the variation related to the update of the Summary of Product Characteristics section 4.4 following the outcome of a follow-up measure concerning the incidence of congenital malformations after Assisted Reproductive Technologies (ART). On 17 January 2002, the CPMP approved the variation (EMEA/H/C/274/II/04). The respective Commission Decision was issued on 18 April 2002.