Steps taken after granting the Marketing Authorisation

- On 8 September 2000 the EMEA approved a change of the package insert not related to the SPC (change of local representative). Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.

- On 24 October 2000 the EMEA approved a Type I No. 30 variation for the 150 mg and the 300 mg strength for an additional pack size of respectively 10 and 8 tablets. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.

- On 29 November 2001 the EMEA approved a Type I No. 1 variation to change the name of the manufacturing authorisation holder from Intervet International B.V, Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands to Intervet GesmbH, Siemensstrasse 105, A 1210 Vienna, Austria. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR. The Commission adopted the decision on 6 February 2002.

- On 29 November 2001 the EMEA approved a Type I No. 16 variation to change the batch size of the finished product. This variation does not require any amendment to the Community Marketing Authorisation.

- On 29 November 2001 the EMEA approved a Type I No. 33 variation to change the size of the 150mg/300mg tablets. This variation does not require any amendment to the Community Marketing Authorisation.

- On 26 February 2003 the EMEA approved a Type I No. 20 variation to extend the shelf life of the 150mg and 300mg tablets from 2 to 3 years. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.

- On 20 March 2003, the Commission Decisions for Ibaflin gel 3% and 7.5% were granted. Intervet had submitted an application on 08 August 2001 pursuant to Annex II of Regulation 542/95 and Article 4(1) of Regulation (EEC) 2309/93 for two strengths of Ibaflin gel 3% and 7.5%

- On 6 June 2003 the EMEA approved a Type I No. 20a variation to extend the retest period of the active substance ibafloxacin from two to five years. This variation does not require any amendment to the Community Marketing Authorisation.

- On 22 December 2003 the EMEA approved a Type IB No. 42 variation to extend the shelf-life of the 150 mg and 300 mg tablets from three to four years. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.

- On 23 February 2004 the Commission Decisions were granted for the extension applications for the 30 mg and 900mg tablets validated on 13 August 2002. A positive Opinion was adopted on 17 September 2003 by the CVMP for these extension applications.

- A Notification for the deletion of the local representatives from the Package Insert was accepted by the EMEA on 16 March 2004 and the corresponding Commission Decision was issued on 7 April 2004.

- On 2 December 2004 the EMEA approved a Type 1A no5 variation to change the address of the manufacturer for Ibaflin tablets, Intervet GesmbH, Vienna, from Siemensstrasse 105 to Siemensstrasse 107.

- On 4 February 2005 the EMEA approved a Type 1B no8 and consequential Type 1A no7 variation to add an additional manufacturing site and site of batch release for the Ibaflin gels at Intervet Productions, Igoville France.

- On 8 July 2005, the European Commission renewed the marketing authorisation for Ibaflin. This decision was based on the favourable opinion and assessment report adopted by the CVMP on 13 April 2005.

- On 17 July 2008 the EMEA approved a Type 1A no 36b variation to change the cap of the syringe for Ibaflin 3% gel (the pin in the middle of the cap will be removed). The cap is already in use for Ibaflin 7% gel.

- On 8 July 2009 the EMEA approved a Type IA-No.38a – Minor change in the test procedure of the finished product- a change to the dose accuracy test for Ibaflin Gel 3%. No annexes were affected by this change.

- On 8 July 2009 the EMEA approved a Type IA-No.7a - Addition of a manufacturing site for the secondary packaging for both Ibaflin gel presentations 3% and 7.5% for the finished product. No annexes were affected by this change.

- On 26 May 2010, the European Commission renewed indefinitely the marketing authorisation for Ibaflin. This decision was based on the favourable opinion and assessment report adopted by the CVMP on 10 March 2010.