

Steps taken after granting the Marketing Authorisation

- On 5 June 2001 the EMEA accepted a Type I variation to comply with Commission Directive 1999/104/EC (TSE compliance). The variation does not require amendment of the Marketing Authorisation.
- An Opinion on a Type II variation to update the product information in accordance with the SPC guideline for immunologicals, in particular to modify the current warning regarding the mineral oil content, was adopted by the CVMP on 9 April 2003. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.
- On 18 April 2005, the Commission approved the transfer of the Marketing Authorisation from "BAYER AG, Business Group Animal Health, D-51368 Leverkusen, Germany" to "Pfizer Ltd., Sandwich, Kent, CT13 9NJ, UK". The name and address of the manufacturers remain unchanged.
- On 20 September 2005 the EMEA accepted a Type IB No. 2 variation to change the name of the medicinal product from Bayovac CSF E2 to Advasure.
- On 13 February 2006, the European Commission renewed the marketing authorisation for a further five years for Advasure. This decision was based on the favourable opinion and assessment report adopted by the CVMP on 7 December 2005.