STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 November 2001 please refer to module 8B.

- The Marketing Authorisation Holder submitted to the EMEA on 9 August 2000 an application for a type I variation falling within the scope of item No. 1 of Annex I to Commission Regulation (EC) No 542/95. The Marketing Authorisation Holder applied to change in the premises of one of the manufacturing sites responsible for batch release. On 20 September 2000, the EMEA issued the corresponding notification (EMEA/H/C/219/I/01). This variation required amendments to annexes II and IIIB of the Community Marketing Authorisation. The respective Commission Decision was issued on 15 January 2001.
- On 20 February 2001, the Marketing Authorisation Holder submitted an application for a type II variation in accordance with the Commission Regulation (EC) No 542/95, as amended. The Marketing Authorisation Holder applied to demonstrate compliance with Commission Directive 1999/82/EC and the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products (CPMP/BWP/1230/98 rev.1), and provided certificates of suitability issued by the European Pharmacopoeia for the materials listed in Annex B. On 18 October 2001, the CPMP approved the variation (EMEA/H/C/219/II/02), which did not require any amendment to the Community Marketing Authorisation.
- Pursuant to Article 13(2) of Council Regulation No. 2309/93 and Part 4G of the Annex to Council Directive 75/318/EEC, the Marketing Authorisation Holder provided throughout the first year of the Marketing Authorisation additional data as stated in Annex IIC to Commission Decision, which formed the basis of the annual re-assessment of the benefit/risk profile of Ammonaps. On 25 January 2001, the CPMP, having reviewed the evidence of compliance with the specific obligations submitted by the Marketing Authorisation Holder and having re-assessed the benefit/risk profile of the medicinal product, informed the European Commission that no updating of Annex I and III to the Community Marketing Authorisation for the medicinal product is required. The CPMP opinion included a revised list of specific obligations of Annex II.C. to the Community Marketing Authorisation (EMEA/H/C/219/S/2). The respective Commission Decision was issued on 6 June 2001.