BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 29 September 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for FOSAVANCE, through the centralised procedure. After agreement by the CHMP on 25 September 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: I. Hudson Co-Rapporteur: J. Suko

2. Scientific Advice:

The applicant received Scientific Advice from the CHMP on 25 July 2002, 26 June 2003 and 15 December 2004. The Scientific Advice pertained to non-clinical and clinical aspects of the dossier.

3. Licensing status:

The product was not licensed in any country at the time of submission of the application.

4. Steps taken for the assessment of the product

- The application was received by the EMEA on 29 September 2004.
- The procedure started on 18 October 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 23 December 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 23 December 2004.
- During the meeting on 15 – 17 February 2005, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 17 February 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 9 March 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 25 April 2005.
- During the meeting on 23-26 May 2005, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to FOSAVANCE on 26 May 2005. The applicant provided the letter of undertaking on the follow-up measure to be fulfilled post-authorisation on 25 May 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 August 2005.