BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 28 June 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ADROVANCE, through the centralised procedure.

The legal basis for this application refers to Article 10c of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder, Merck Sharp & Dohme Ltd., for the authorised medicinal product FOSAVANCE (EU/1/05/310/001-005).

Licensing status:
The initial product, FOSAVANCE, has been given a Community Marketing Authorisation on 24 August 2005.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Ian Hudson Co-Rapporteur: Josef Suko

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 28 June 2006.
- The procedure started on 21 July 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 September 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 22 September 2006.
- The Rapporteur circulated an updated Assessment Report to all CHMP members on 13 October 2006.
- The applicant provided on 17 October 2006 a letter of undertaking of the follow-up measures to be fulfilled post-authorisation.
- During the meeting on 16-18 October 2006, 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 ADROVANCE on 18 October 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 4 January 2007.