BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Amgen Europe B.V. submitted on 2 July 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Kepivance, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:

Rapporteur: Ian Hudson Co-Rapporteur: Tomas Salmonson

Licensing status:

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

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 2 July 2004.
- The procedure started on 19 July 2004.
- The initial Rapporteur's Assessment Report was circulated to all CHMP members on 1 October 2004 and an updated Overview Assessment Report on the 8 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 28 September 2004.
- During the meeting on 16-18 November 2004, 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 18 November 2004.
- A clarification meeting with the Rapporteur and Co-Rapporteur on the CHMP List of Questions was held on 17 January 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 18 March 2005.
- The summary reports of the inspection carried out at the manufacturing Amgen sites (1 and 2) was signed by inspectors on 30 December 2004, and for the manufacturing Baxter site (3) was signed by the inspectors on 3 November 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 6 May 2005.
- During the 10-11 May 2005 meeting the BWP adopted the BWP report with a recommendation to the CHMP to incorporate additional questions in the CHMP list of outstanding issues.
- During the CHMP meeting on 23-26 May 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- A clarification meeting (teleconference) with the Rapporteur and Co-Rapporteur on the CHMP list of outstanding issues was held on 1 June 2005.
- The applicant submitted the responses to the CHMP list of outstanding issues on 17 June 2005.
- The Rapporteurs circulated the updated Joint Assessment Report on the applicant’s responses to the List of Outstanding Issues on 4 July 2005.
- The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 July 2005.
- During the meeting on 25-28 July 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 Kepivance on 27 July 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 25 October 2005.