BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant The Medicines Company UK Ltd. submitted on 29 July 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Angiox, through the centralised procedure. After agreement by the CHMP on 23 January 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: Dr I. Hudson Co-Rapporteur: Dr G. Calvo Rojas

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

Angiox has been given a Marketing Authorisation in the United States on 15 December 2002, in Canada on 9 October 2002, in New Zealand in October 1999, in Israel in July 2002 and in Argentina in March 2002.

2. Steps taken for the assessment of the product

- The procedure started on 18 August 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 October 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 6 November 2003.
- During the meeting on 16 – 17 December 2003, 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 December 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 February 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 March 2004.
- During the CHMP meeting on 20 – 22 April 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 30 April 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 25 May 2004.
- The Rapporteurs circulated the revised Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 17 June 2004.
- During the meeting on 22 – 23 June 2004, 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 Angiox on 23 June 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 21 June 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 September 2004.