BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Sanofi Synthelabo submitted on 14 February 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Arixtra, through the centralised procedure. After agreement by the CPMP on 30 June 2000, 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 CPMP were:

Rapporteur: Dr Per Nilsson Co-Rapporteur: Prof Silvio Garattini

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 21-22 October 1997. The Scientific Advice pertained to part IV of the dossier.

Licensing status:

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

1.2 Steps taken for the assessment of the product

- The procedure started on 1 March 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 8 May 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 10 May 2001 (Annex 2)
- During the meeting on 26-28 June 2001 the CPMP 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 27 June 2001 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 9 August 2001.
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 27 September 2001 (Annex 5)
- During the CPMP meeting on 14 November 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 11-13 December 2001 the CPMP, 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 Arixtra on 13 December 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 21 March 2002.