BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer AG submitted on 28 December 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Levitra, through the centralised procedure. After agreement by the CPMP on 31 May 2001, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Gonzalo Calvo Rojas Co-Rapporteur: Barbara van Zwieten-Boot

Licensing status:

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

2. Steps taken for the assessment of the product

- The procedure started on 28 January 2002.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 12 April 2002. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 10 April 2002.
- During the meeting on 28-30 May 2002 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 31 May 2002.
- The company submitted the responses to the consolidated list of questions on 13 September 2002.
- 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 21 October 2002.
- During the meeting on 19-21 November 2002 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 Bayer AG on 21 November 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 6 March 2003.