BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration Limited submitted on 1 July 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Bonviva, through the centralised procedure. After agreement by the CPMP on 21 February 2002, 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 and the evaluation teams were:

Rapporteur: Dr Mark Ainsworth Co-Rapporteur: Prof. Heribert Pittner

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 22 July 2002.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 2 October 2002. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 2 October 2002.
- During the meeting on 19-21 November 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 21 November 2002.
- The company submitted the responses to the consolidated list of questions on 16 April 2003.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 26 May 2003.
- During the CPMP meeting on 24-26 June 2003, the CPMP agreed on a list of outstanding issues to be addressed in writing by the applicant (Annex 5).
- The company submitted the responses to the CPMP consolidated List of Outstanding issues on 25 July 2003
- During the meeting on 21-23 October 2003 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 Bonviva (ibandronic acid) on 23 October 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 23 February 2004.