BACKGROUND INFORMATION ON THE PROCEDURE

1.   Submission of the dossier

The company Schering AG submitted on 7th March 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Zevalin, 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 CPMP were:

Rapporteur: Dr Jens Ersbøll   Co-Rapporteur: Dr Barbara van Zwieten-Boot

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 25 April 2001. The Scientific Advice pertained to part IV of the dossier and was implemented by the Company.

Licensing status

Zevalin was licensed in the USA on 19 February 2002.

2.   Steps taken for the assessment of the product

- The procedure started on 24 March 2003.

- The Rapporteur and Co-Rapporteur circulated a joint Assessment Report to all CPMP members on 4 June 2003.

- During the meeting on 22-24 July 2003 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 23 July 2003.

- The summary report of the inspection carried out at the manufacturing site IDEC Pharmaceuticals Corp on 12-14 May 2003 was issued on 18 July 2003.

- The company submitted the responses to the CPMP consolidated List of Questions on 12 August 2003.

- The Rapporteur and Co-Rapporteur circulated the response Joint Assessment Report on the company's responses to the List of Questions to all CPMP members on 5 September 2003.

- During the meeting on 23-25 September 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 Zevalin on 25 September 2003.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 16 January 2004.