BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Hospira Enterprises B.V. submitted on 11 May 2007 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Retacrit, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.
The legal basis for this application refers to:

Article 10(4) of Directive 2001/83/EC, as amended – relating to applications for a biosimilar medicinal products.

The application submitted is a complete dossier:
composed of administrative information, complete quality data, appropriate non-clinical and clinical data for a similar biological medicinal product.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 22 March 2004 and 15 September 2005. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:

Rapporteur: **Harald Enzmann** Co-Rapporteur: **Ian Hudson**

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 11 May 2007.
- The procedure started on 19 July 2006.
- This application forms part of a multiple application for epoetin zeta. The initial application was submitted by STADA Arzneimittel AG (EMEA/H/C/760). The review process for both applications was integrated at the time of List of Questions, allowing the CHMP opinion to be adopted in the same timeframe as EMEA/H/C/760.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 03 July 2007
- During the CHMP meeting on 16-19 July 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- During the meeting on 15-18 October 2007, 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 Retacrit on 18 October 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 17 October 2007