BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

BioPartners GmbH submitted on 3 June 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Valtropin through the centralised procedure under the legal base of Similar Biological Medicinal Product under Article 10(1)(a)(iii) of Directive 2001/83/EC, and with reference to Part II.4 of Annex I of Directive 2001/83/EC, as amended.

The procedure was finalised with the adoption of the opinion according to Article 10(4) of Directive 2001/83/EC, as amended – relating to applications for similar biological medicinal products.

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 17 December 1998. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

Licensing status:

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

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr H. Enzmann
Co-Rapporteur: Dr F. Lekkerkerker

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 3 June 2004. The legal base for the application was Article 10(1)(a)(iii) of Directive 2001/83/EC and with reference to Part II.4 of Annex I of Directive 2001/83/EC, as amended. Following the entry into force of Directive 2004/27/EC, Article 10(1)(a)(iii) has been replaced by Article 10.4.
- The procedure started on 19 July 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 6 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 5 October 2004.
- During the meeting on 15-18 November 2004, the CHMP 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 18 November 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 5 September 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 21 October 2005.
- During the CHMP meeting on 15-17 November 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 9 December 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 12 January 2006.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 31 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 10 February 2006.
- During the meeting on 20-23 February 2006, 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 Valtropin on 23 February 2006. The applicant provided

the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 February 2006.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 April 2006.