BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Sandoz GmbH submitted on 1 July 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Omnitrope, through the centralised procedure under the legal base of Similar Biological Medicinal Product referring to Article 10.4 of Directive 2004/27/EC.

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

Rapporteur: Dr Frits Lekkerkerker Co-Rapporteur: Dr Harald Enzmann

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 application was received by the EMEA on 1 July 2004. The legal base for the application was Similar Biological Medicinal Product referring to Article 10.4 of Directive 2004/27/EC.
- The procedure started on 16 August 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 29 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 26 October 2004.
- During the meeting on 13-16 December 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 16 December 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 4 February 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 24 March 2005.
- During the CHMP meeting on 18-21 April 2005, 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 20 May 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 9 June 2005.
- The BWP during its meeting of 13-15 June 2005 adopted the BWP Report to be transmitted to the CHMP for endorsement.
- During the CHMP meeting on 20-23 June 2005, the CHMP agreed on a list of outstanding issues (Following assessment of responses to Day 180 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 1 July 2005.
- The BWP during its meeting of 18-20 July 2005 adopted the BWP Report to be transmitted to the CHMP for endorsement.
- During the CHMP meeting on 25-28 July 2005, the CHMP discussed the responses to the outstanding issues.
- During the CHMP meetings of September, November and December 2005, updates were provided with regard to the responses to the outstanding issues.
- During January 2006, the outstanding issues were clarified in a satisfactory manner.
- The applicant submitted a revised Letter of Undertaking, 23 January 2006.
- During the meeting on 23-26 January 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 Omnitrope on 26 January 2006.