BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Oxford GlycoSciences (UK) Ltd submitted on 29 June 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) through the centralised procedure for Zavesca, which was designated as an orphan medicinal product EU/3/00/006 on 18 October 2000.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr Per Nilsson Co-Rapporteur: Prof Rolf Bass

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 17 July 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 26 September 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 27 September 2001.
- During the meeting on 13 – 15 November 2001 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 15 November 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 23 January 2002.
- The summary report of the inspection carried out at the manufacturing site on 11 December 2001 was issued on 12 February 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 25 February 2002.
- During the meeting on 19 – 21 March 2002 the CPMP adopted a list of outstanding issues to be addressed by the applicant in writing. The list of outstanding issues was sent to the applicant on 21 March 2002.
- The applicant provided written information on these outstanding issues to all CPMP members on 26 April 2002 and 15 May 2002. The Rapporteur/Co-Rapporteurs' joint review on the responses to the list of outstanding issues was circulated to all CPMP members on 14 May 2002 and an amended version on 22 May 2002.
- Concurrent with the CPMP meeting on 25 - 27 June 2002, an ad-hoc clinical expert meeting took place on 24 June 2002 and a report was adopted by the CPMP on 27 June 2002.
- During the CPMP meeting on 25 – 27 June 2002, outstanding issues were addressed by the applicant on 25 June 2002 during an oral hearing before the CPMP.
- The applicant provided written information to all CPMP Members on 15 July 2002. The Rapporteur/Co-Rapporteurs' joint review of the written information was circulated to all CPMP members on 16 July 2002.
- During the meeting on 23 – 25 July 2002 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 Zavesca on 25 July 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 November 2002.