BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Celltech Pharmaceuticals Ltd submitted on 11 March 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Xyrem which was designated as an orphan medicinal product EU/3/02/31 on 03 February 2003. On 30 December 2004 the EMEA was notified that following acquisition of Celltech by UCB Pharma, the ownership rights for Xyrem application were transferred to UCB Pharma..

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

Rapporteur: Prof Cristina Sampaio Co-Rapporteur: Dr Jens Ersbøll

Licensing status:

Xyrem has been given a Marketing Authorisation in The United States of America on 17 July 2002. Applications were filed in the following countries: Canada and Switzerland.

2. Steps taken for the assessment of the product

- The procedure started on 29 March 2004.
- The Rapporteur's and Co-Rapporteur's first Assessment Report were circulated to all CHMP members on 15 June 2004 .
- During the meeting on 27-29 July 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 29 July 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 March 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 16 May 2005.
- An expert panel meeting was convened on 23 May 2005.
- During the CHMP meeting on 23-26 May 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 02 June 2005.
- During the meeting on 20-23 June 2005, 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 Xyrem on 23 June 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 23 June 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 October 2005.