BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Glaxo Group Limited submitted on 19 December 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Telzir, through the centralised procedure. After agreement by the CPMP on 25 July 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr E. Abadie Co-Rapporteur: Dr J.L. Robert

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 20 January 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 4 April 2003 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 31 March 2003
- During the meeting on 20 – 22 May 2003, 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 22 May 2003
- The applicant submitted the responses to the CPMP consolidated List of Questions on 19 November 2003.
- The (Co)-Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 23 December 2003
- During the CPMP meeting on 20 – 22 January 2004, the CPMP agreed on a list of outstanding issues to be addressed in writing by the applicant
- The applicant submitted the responses to the CPMP list of outstanding issues on 1 March 2004.
- The (Co)-Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding issues to all CPMP members on 16 March 2004
- During the meeting on 23 – 24 March 2004, 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 Telzir on 24 March 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 March 2004
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 12 July 2004.