BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Les Laboratoires Servier submitted on 25 June 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Protelos, through the centralised procedure. After agreement by the CPMP on 19 March 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Dr. Per Nilsson Co-Rapporteur: Prof. Josef Suko

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 21 July 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 1 October 2003 . The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 6 October 2003
- During the meeting on 20 November 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 20 November 2003 .
- The applicant submitted the responses to the CPMP consolidated List of Questions on 12 February 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 19 March 2004
- During the CPMP meeting on 22 April 2004, the CPMP agreed on a list of outstanding issues to be addressed in writing by the applicant
- The applicant submitted written answers to the list of outstanding issues on 14 May 2004.
- The Rapporteurs circulated a revised Joint Assessment Report on the applicant's written responses to the list of outstanding issues on 28 May 2004
- Following a request by the Rapporteurs the PhWP reviewed the pharmacovigilance plan for Protelos during the meeting on 22 June 2004.
- The PhWP report on the pharmacovigilance plan for Protelos was circulated to all CPMP members on 22 June 2004
- The applicant submitted a revised Pharmacovigilance plan on 22 June 2004 that was subsequently discussed and agreed by CHMP
- During the meeting on 22-23 June 2004, 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 Protelos on 23 June 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 21 June 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding decisions on 21 September 2004.