BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alexion Europe SAS submitted on 25 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Soliris, through the centralised procedure falling within the Article 3(1) and point 1 and 4 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 30 March 2006.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier:

composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain tests or studies

Soliris was designated as an orphan medicinal product EU/3/03/166 on 17 October 2003 in the following indication: treatment of patients with paroxysmal nocturnal haemoglobinuria. The calculated prevalence of this condition was 0.01 per 100,000 EU population.

The applicant applied for the following indication: Soliris (eculizumab) is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH).

Protocol Assistance:
The applicant received Protocol Assistance from the CHMP on 18 November 2004 and 23 February 2006. The Protocol Assistance pertained to biological, toxico-pharmacological and clinical development aspects of the dossier.

Licensing status:
A new application was filed in the following countries: U.S.A.
The product was not licensed in any country at the time of submission of the application.

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

Rapporteur: Gonzalo Calvo Rojas (ES) Co-Rapporteur: Eric Abadie (FR)

2. Steps taken for the assessment of the product

- Accelerated Assessment procedure was agreed-upon by CHMP on 29 June 2006.
- The application was received by the EMEA on 25 September 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 21 January 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 23 January 2007.
- During the meeting on 19-22 February 2007, 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 22 February 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 20 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 10 April 2007.
- During the meeting on 23-26 April 2007, 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 Soliris on 26 April 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 25 April 2007.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 June 2007.