BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Astellas Pharma GmbH submitted on 18 January 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Advagraf, through the centralised procedure under Article 3 (2) (b) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 14 December 2005.

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 test or study.

Licensing status:
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 the evaluation teams were:
Rapporteur: Dr David Lyons Co-Rapporteur: Romaldas Maciulaitis

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 18 January 2006.
- The procedure started on 1 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 22 May 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 22 May 2006.
- During the meeting from 26-28 June 2006, 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 June 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 28 September 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 10 November 2006.
- During the CHMP meeting on 11-14 December 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted written explanations to the CHMP List of Outstanding Issues on 26 January 2007.
- During the meeting from 19-22 February 2006 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 Advagraf on 22 February 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 23 April 2007.