BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Pharma EEIG submitted on 2 December 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ORENCIA, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

The legal basis for this application refers to:

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

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
A new application was filed in the following countries: USA and Canada.
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 were:

Rapporteur: **Pekka Kurki** Co-Rapporteur: **János Borvendég**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 2 December 2005.
- The procedure started on 28 December 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 8 March 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 7 March 2006.
- The quality list of questions was discussed and adopted at the Biological Working Party (BWP) meeting of 19-20 April 2006.
- During the meeting on 24-27 April 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 27 April 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 4 October 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 13 November 2006.
- The quality list of outstanding issues was discussed and adopted at the Biological Working Party (BWP) meeting of 4-6 December 2006.
- During the CHMP meeting on 13-14 December 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 25 January 2007.
- During the BWP meeting on 12-14 February 2007, outstanding issues were addressed by the applicant during an oral explanation before the BWP and a recommendation to the CHMP was adopted.
- During the CHMP meeting on 19-22 February 2007, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- The Rapporteurs circulated the Final Joint Assessment Report on the applicant’s responses to the remaining items of the List of Outstanding issues to all CHMP members on 08 March 2007.

- During the meeting on 19-22 March 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 ORENCIA on 22 March 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 March 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 21 May 2007.