I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hoechst Marion Roussel Deutschland GmbH submitted on 6 February 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Arava, through the centralised procedure. The name of the Marketing Authorisation Holder has been changed from Hoechst Marion Roussel Deutschland GmbH to Aventis Pharma Deutschland GmbH (see steps after the Marketing Authorisation). After agreement by the CPMP on 20 May 1999, 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 and the evaluation teams were:

Rapporteur:	Dr Hans van Bronswijk	Co-Rapporteur:	Pharm. G. De Greef
Evaluators:	Dr O. A. Lake (Quality)	Evaluators:	Prof. Y. Michotte (Quality)
	Dr. J. G. C. Van Amsterdam (Safety)		Dr. P. Poukens-Renwart (Quality)
	Dr F. van Zoest (Safety)		Dr W. Penninckx (Quality)
	Dr. S. de Boer (Safety)		Dr M. Zeicher (Safety)
	Dr H. W. Nab (Efficacy)		Dr A. Lhoir (Efficacy)
	Dr P. Baede-van Dijk (Efficacy)		

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 24 February 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 29 April 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 11 May 1998.
- During the meeting on 23-25 June 1998 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 25 June 1998.
- The applicant submitted the responses to the consolidated list of questions on 4 December 1998.
- The Rapporteur/Co-Rapporteur circulated the response assessment report on the applicant's responses to the list of questions to all CPMP Members on 20 January 1999.
- The applicant requested on 05 February 1999 a clock stop until the April 1999 CPMP meeting. This request was agreed at the CPMP meeting on 25 February 1999.
- List of outstanding issues was adopted at the CPMP meeting on 25 February 1999.
- The applicant provided supplementary information on 22 March 1999.
- During the meeting on 23-25 March 1999 the CPMP agreed that no inspection or sampling was necessary.
- The applicant gave an oral presentation on 20 April 1999 during the CPMP meeting and the remaining issues were presented.
- A draft list of questions to be addressed by the applicant has been adopted at the CPMP meeting on 22 April 1999 and the clock was stopped.
- The applicant submitted the responses to the remaining list of questions along with a new SPC and PIL on 04 May 1999.

- During the meeting on 18-20 May 1999 the CPMP, in the light of the overall data submitted and the scientific discussion within the committee, issued a positive opinion by majority vote for granting a Marketing Authorisation to Arava on 20 May 1999.
- During the CPMP meeting on 20 May 1999 a letter of undertaking has been adopted.
- The CPMP Opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 02 September 1999.

II. GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisation holder and inspection status

Manufacturer of the active substance

Aventis Pharma Deutschland GmbH
Industriepark Höchst
D-65926 Frankfurt/Main
Germany

Manufacturer of the finished medicinal product

Hoechst Marion Roussel-Usiphar
56 route de Choisy au Bac
F-60205 Compiègne
France

Manufacturer responsible for batch release in the European Economic Area

Aventis Pharma Deutschland GmbH
Industriepark Höchst
D-65926 Frankfurt/Main
Germany

The Manufacturing authorisation was issued on 12 May 1998 by Regierungspräsidium, Darmstadt, Germany.

2. Conditions or restrictions regarding supply and use

Medicinal product subject to restricted medical prescription (see section 4.2 of the SPC).

3. Follow Up measures of the marketing authorisation holder

The applicant agreed to provide additional information within the agreed timeframe as indicated in the letter of undertaking (dated 29 April 1999).