BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratoires 3M Santé, France submitted on 20 May 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for ALDARA, through the centralised procedure. After agreement by the CPMP on 12-14 March 1996, this medicinal product was referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.
The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. D. Jefferys Co-Rapporteur: Dr. E. Abadie

Licensing status

The product was authorised in the USA on 27 February 1997.

2. Steps taken for the assessment of the product

- The procedure started on 20 June 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 6 August 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 1 September 1997.
- During the meeting on 21-22 October 1997, the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 22 October 1997.
- The company submitted the responses to the consolidated list of questions on 9 January 1998.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 2 March 1998.
- During it's meeting on 21-22 April 1998, the CPMP agreed on a list of outstanding issues (request for a reference drug comparative trial, risk in uncircumcised male patients, risk/benefit in treatment of recurrent ano-genital warts) to be addressed by the company in an oral explanation.
- The company submitted written responses on the outstanding issues on 4 May 1998.
- The CPMP, during its meeting on 26-27 May 1998 considered the responses provided by the company and discussed the recommendations presented by the Rapporteur and Co-Rapporteur. Amendments to the Special warnings and special precautions for use section of the Summary of Product Characteristics, and Package Leaflet text were discussed. The outstanding issues were resolved and a hearing was not considered necessary.
- During the meeting on 26-27 May 1998 the CPMP, 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 ALDARA on 27 May 1998**.**
- The CPMP Opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 18 September 1998.