

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merial submitted on 2 December 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Purevax RC, in accordance with the centralised procedure falling within the scope of Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CVMP were:

Rapporteur: Bruno Urbain

Co-Rapporteur: Ricardo de la Fuente

Licensing status (outside EEA):

On 2 December 2003, 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 17 December 2003.
- The Rapporteur's first assessment report was circulated to all CVMP Members on 24 February 2004. The Co-Rapporteur's first assessment report was circulated to all CVMP Members on 10 March 2004.
- During the meeting on 13-15 April 2004 the CVMP 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 15 April 2004.
- The company submitted the responses to the consolidated list of questions on 15 July 2004.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CVMP Members on 24 August 2004.
- During the meeting on 9-11 November 2004 the CVMP, 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 Purevax RC on 10 November 2004.
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 23 February 2005.