I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Intervet International B.V. submitted on 2 September 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Nobivac Piro, through the centralised procedure. After agreement by the CVMP on 12 May 2004, this veterinary 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 CVMP and the evaluation teams were:

Rapporteur: Dr. J.-C. Rouby Co-Rapporteur: Dr. M. Ilott

Licensing status (outside EEA):

On 17 September 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 September 2003.
- The Rapporteur's first assessment report was circulated to all CVMP Members on 25 November 2003. The Co-Rapporteur's first assessment report was circulated to all CVMP Members on 10 December 2003
- During the meeting on 13-15 January 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 January 2005.
- The company submitted the responses to the consolidated list of questions on 12 February 2004.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CVMP Members on 23 March 2004.
- During the meeting on 11-13 May 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 Nobivac Piro on 12 May 2004.
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 2 September 2004.