I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company ECO Animal Health submitted on 29 July 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Aivlosin, through the centralised procedure. After agreement by the CVMP on 9 April 2003, 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: J. O'Brien from the UK and E. Johnsson from Sweden.

Licensing status (outside EEA):

On 29 July 2003, Aivlosin has been given a Marketing Authorisation in Argentina, China, Columbia, Costa Rica, Dominican Republic, Guatemala, India, Iran, Japan, Mexico, Panama, Peru, Philippines, South Africa, Thailand, Venezuela and Vietnam.

On 29 July 2003, an application for a marketing authorisation was pending in the following countries: Bangladesh, Chile, Cuba, Egypt, El Salvador, Honduras, Indonesia, Israel, Pakistan, Saudi Arabia, Switzerland, Taiwan, Trinidad and Tobago.

2. Steps taken for the assessment of the product

- The procedure started on 13 August 2003.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on respectively 21 October 2003 and 5 November 2003.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 10 December 2003 was sent to the applicant and the clock stopped.
- The applicant circulated the responses to the CVMP list of questions on 15 Jan 2004 and the clock was restarted on 16 Jan 2004.
- The joint Rapporteur and Co-rapporteur assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 24 Feb 2004.
- The joint Rapporteur and Co-rapporteur assessment report was discussed during the meeting of the CVMP held on 17 March 2004 and the Committee agreed to ask the Applicant for oral and written explanations.
- Oral and written explanations to outstanding issues were provided by the applicant on 15 April 2004.
- During the meeting 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 for Aivlosin 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 9 September 2004.