I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Virbac S.A. on 22 October 2007, the CVMP accepted on 11-13 December 2007 that Leucofeligen FeLV/RCP was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The Committee for Medicinal Products for Veterinary Use appointed Dr Manfred Moos from Germany as Rapporteur and Dr Martin Ilott from United Kingdom as Co-Rapporteur for the assessment of the application for Leucofeligen FeLV/RCP during its meeting of 11-13 December 2007. During the assessment procedure Dr Anna-Maria Brady subsequently replaced Dr Ilott as Co-Rapporteur.

The company Virbac S.A. submitted an application to the EMEA on 4 March 2008 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 18 March 2008.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 15-17 July 2008 was sent to the Applicant and the clock stopped.
- The consolidated list of outstanding issues as agreed by the CVMP during its meeting held on 10-12 February 2009 was sent to the Applicant.
- The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 11 March 2009 a positive Opinion for the granting of a Community marketing authorisation for Leucofeligen FeLV/RCP.

The European Commission granted a marketing authorisation valid throughout the European Union for Leucofeligen FeLV/RCP on 25 June 2009.