I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Bayer HealthCare AG on 17 November 2003, the Committee for Veterinary Medicinal Products (CVMP) accepted on 9 – 11 December 2003 that Profender was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 2309/93.

The CVMP appointed Mr R. Breathnach from Ireland as Rapporteur and Dr L. Meisel from Portugal as Co-Rapporteur for the assessment of the application for Profender during its meeting of 9 – 11 December 2003.

The company Bayer HealthCare AG submitted an application to the EMEA on 2 March 2004 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 16 March 2004.

2. Steps taken for the assessment of the product

- The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on respectively 25 May 2004 and 09.06.04.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 13-15 July 2005 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 14 October 2004 and the clock was restarted on 15 October 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 23 November 2004.
- Written and oral explanations on the outstanding issues were provided by the applicant on 21 January 2005 and 9 February 2005 respectively.
- 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 a positive opinion for the granting of a Community Marketing Authorisation for Profender on 9 March 2005.
- At their May 2005 meeting, the CVMP confirmed the positive opinion further to an appeal by the Applicant regarding a change in the wording of the Package Insert and a minor change to the wording of the Labelling.
- The CVMP Opinions were forwarded, in all official languages of the European Union, to the European Commission. The corresponding Commission Decisions were adopted on 27 July 2005.