I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd. on 26 October 2007, the CVMP accepted on 12 December 2007 that Palladia was eligible for the submission of a dossier for granting of a Community marketing authorisation under Article 3(2)(a) (new active substance) of Regulation (EC) No 726/2004.

The Committee for Medicinal Products for Veterinary Use appointed Dr Karolina Törneke from Sweden as Rapporteur and Dr Cornelia Ibrahim from Germany as Co-Rapporteur for the assessment of the application for Palladia during its meeting of 11-13 December 2007.

The company Pfizer Ltd. submitted an application to the EMEA on 30 April 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 20 May 2008.

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

Rapporteur: Dr Karolina Törneke from Sweden: Co-Rapporteur Dr Cornelia Ibrahim from Germany

2. Steps taken for the assessment of the product

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 18 July 2008 and 13 August 2008, respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held in September 2008 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 16 January 2009 and the clock was restarted.
- 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 February 2009.
- An oral explanation was held on 13 May 2009.
- 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 17 June 2009, a positive Opinion for the granting of a Community Marketing Authorisation for Palladia.