I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Laboratorios Hipra, S.A. on 20 June 2006, the CVMP accepted on 19 July 2006 that Startvac was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The **Rapporteur and Co-Rapporteur** appointed by the CVMP were:
Rapporteur: Manfred Moos from Germany and Co-Rapporteur: Consuelo Rubio Montejano from Spain.

The company LABORATORIOS HIPRA, S.A. submitted an application to the EMEA on 27 April 2007 for the granting of a Community marketing authorisation for STARTVAC in accordance with Regulation (EC) No 726/2004.

The application was validated on 15 May 2007

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 12 September 2007 was sent to the Applicant and the clock stopped.
- 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 10 December 2008 a positive Opinion for the granting of a Community marketing authorisation for Startvac.

The European Commission granted a marketing authorisation valid throughout the European Union for Startvac on 11 February 2009.