I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Fort Dodge Animal Health on 1 August 2007, the CVMP accepted in September 2007 that Suvaxyn PCV 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: Dr Frédéric Descamps from Belgium: Co-Rapporteur Dr Ellen-Margrethe Vestergaard from Denmark

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 30 April 2008
- The procedure started on 21 May 2008
- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on respectively 29 July 2008 and 13 August 2008.
- During its meeting in September 2008 the CVMP agreed on List of Questions.
- The Applicant submitted the responses to the CVMP List of Questions on 12 February 2009.
- The Rapporteur's circulated their joint Assessment Report on the applicant's responses to the List of Questions to all CVMP Members on 23 March 2009.
- During their plenary meeting held from 15-17 April 2009, the CVMP agreed a List of Outstanding Issues.
- During their plenary meeting held from 12 – 14 May 2009, the CVMP considered the responses given by the applicant in writing .
- On 13 May 2009, the CVMP, having considered the overall data submitted and the scientific discussion within the Committee, recommended the granting of a marketing authorisation for Suvaxyn PCV.