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 9 February 2007, the CVMP accepted on 14 March 2007 that Duvaxyn WNV was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

During its meeting of 13-15 March 2007, the Committee for Medicinal Products for Veterinary Use appointed Dr Jean-Claude Rouby from France as Rapporteur and Dr Maria Tollis from Italy as Co-rapporteur for the assessment of the application for Duvaxyn WNV.

The company Fort Dodge Animal Health submitted an application to the EMEA on 31 July 2007 for the granting of a Community marketing authorisation for Duvaxyn WNV in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

2. Steps taken for the assessment of the product

- The application was validated on 14 August 2007 and the clock started on 15 August 2007.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 11-13 December 2007 was sent to the Applicant and the clock stopped.
- A CVMP Opinion was adopted on 17 September 2008, recommending the granting of the Marketing Authorisation for the above mentioned product.
- The European Commission granted a marketing authorisation valid throughout the European Union for Duvaxyn WNV on 21.11.2008.