I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Merial SAS on 21 November 2008, the CVMP accepted on 10 December 2008 that Gripovac 3 was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The CVMP confirmed that the product, a new trivalent swine flu vaccine which contains all important subtypes of swine influenza including the newly emerged H1N2 subtype, would be eligible for the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004, as the product contains a new active substance which was not authorised in the Community on the date of entry into force of the Regulation. The new active substance is the H1N2 subtype, as existing products do not sufficiently alleviate suffering from swine influenza in line with the CVMP Position Paper on definition of a new biological active substance (CVMP/IWP/029/97 FINAL) second indent.

The Committee for Medicinal Products for Veterinary Use appointed Dr Anja Holm from Denmark as Rapporteur and Dr Frédéric Descamps from Belgium as Co-Rapporteur for the assessment of the application for Gripovac 3 during its meeting of 9-11 December 2008.

The company Merial SAS submitted an application to the EMEA on 3 March 2009 for the granting of a Community marketing authorisation 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 10 March 2009.
- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 17 April 2009 and 24 April 2009 respectively.
- The CVMP adopted a List of Questions on 13 May 2009.
- The company provided responses to the List of Questions on 13 August 2009.
- The CVMP adopted a positive opinion on 11 November 2009.