3 September 2010
EMA/544561/2010
Veterinary Medicines and Product Data Management

1. Background information on the procedure

1.1. Submission of the dossier

Further to the submission of a letter of intent by Laboratorios Hipra S.A. on 8 September 2008, the CVMP accepted on 15 October 2008 that RHINISENG was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure under Article 3 paragraph 1 of Regulation (EC) No 726/2004 as one of the antigens (*Pasteurella multocida* toxin) is obtained through recombinant DNA technology.

The Committee for Medicinal Products for Veterinary Use appointed Dr Anja Holm from Denmark as Rapporteur and Dr Gabriel Beechinor from Ireland as Co-Rapporteur for the assessment of the application for RHINISENG during its meeting of October 2008.

The company Laboratorios Hipra S.A. submitted an application to the EMEA on 2 June 2009 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

1.2. Steps taken for the assessment of the product

- The application was validated on 16 June 2009 and the clock started on 17 June 2009.
- The CVMP adopted a consolidated List of Questions on 14 October 2009.
- The company responded to the List of Questions on 14 April 2010.
- A CVMP Opinion was adopted on 14 July 2010 recommending the granting of the Marketing Authorisation for RHINISENG.