EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 August 2010
EMA/540960/2010EMA/540960/2010
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 Ceva Sante Animale in November 2006, the CVMP accepted in December 2006 that COXEVAC was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure as a MUMS product.

The Committee agreed that the product would be eligible for the centralised procedure under both Article 2(a) and (b) 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 and as the product is in the interests of patients and animal health at Community level since it should reduce the risk of human infection and consequently the chance of development of Q-fever.

The rapporteur and co-rapporteur appointed by the CVMP were:

Rapporteur: Dr Jean-Claude Rouby from France, Co-rapporteur: Ms Consuelo Rubio Montejano from Spain.

## *1.2. Steps taken for the assessment of the product*

- The application was submitted to the EMA on 3 December 2008
- The application was validated on 17 December 2008. and the clock started on 18 December 2010.
- The CVMP adopted a consolidated List of Questions on 16 April 2009.
- The company responded to the List of Questions on 15 October 2009.
- An oral explanation was held on 16 June 2010.
- A CVMP opinion was adopted on 14 July 2010 recommending the granting of the Marketing Authorisation under exceptional circumstances for COXEVAC.