I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The legal basis for this application refers to Article 13(1) of Directive 2001/82/EC, as amended by Directive 2004/28/EC of the European Parliament and of the Council. The application concerns a generic medicinal product as defined in Article 13(2)(b) of Directive 2001/82/EC, as amended by Directive 2004/28/EC, and refers to a reference veterinary medicinal product with a Marketing Authorisation granted in the Community.

The chosen reference veterinary medicinal product is Metacam 5 mg/ml solution for injection for cattle and pigs, Marketing Authorisation Holder: Boehringer Ingelheim Vetmedica.

2. Steps taken for the assessment of the product

Further to the submission of a letter of intent by Dopharma Research B.V. on 10 January 2008, the CVMP accepted at the meeting of 12-14 February 2008 that Melovem was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The Committee for Medicinal Products for Veterinary Use appointed Dr. Rory Breathnach from Ireland as Rapporteur and Dr. Anja Holm from Denmark as Co-Rapporteur for the assessment of the application for Melovem during its meeting of 12-14 February 2008.

The company Dopharma Research B.V. submitted an application to the EMEA on 1 July 2008 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

Supplementary information was provided by the applicant on 12 February 2009.
Written explanations were provided by the applicant on 17 April 2009.

The procedure was finalised on 13 May 2009 with adoption of the CVMP opinion.