I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Merial S.A.S. on 30 June 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 13 July 2005 that Circovac was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Regulation (EC) No. 726/2004.

The CVMP appointed Dr Maria Tollis from Italy as the Rapporteur and Dr Martin Ilott from the United Kingdom as the Co-Rapporteur for the assessment of the application for Circovac during its meeting of 12-13 July 2005.

The company Merial S.A.S. submitted an application to the EMEA on 7 December 2005 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on 21 December 2005.

2. Steps taken for the assessment of the product

The consolidated list of questions as agreed by the CVMP during its meeting held on 19 April 2006 was sent to the Applicant and the clock stopped.

The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 17 April 2007 a positive Opinion for the granting of a Community marketing authorisation for Circovac.

The European Commission granted a marketing authorisation valid throughout the European Union for Circovac on 21 June 2007.

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Mérial, Laboratoire Lyon Gerland
254, Avenue Marcel Mérieux
69007 Lyon
France

Name and address of the manufacturer responsible for batch release

Mérial Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

The following substances contained in the final product are included in Annex II of Council Regulation (EEC) No 2377/90:

Substance	MRL status	Comments
Light liquid paraffin	Included in Annex II for all food producing species	Mineral hydrocarbons, low to high viscosity including microcrystalline waxes, approximately C10-C60; aliphatic, branched aliphatic and alicyclic compounds. CR No 2804/95
Thiomersal	Included in Annex II for all food producing species	For use only as preservatives in multidose vaccines at a concentration not exceeding 0.02 %. Cr No 749/97
Adjuvant		
Sorbitan oleate (sorbitan monoleate)	Included in Annex II for all food producing species	Approved food additive (E 494) CR No 2034
Polysorbate 85 (Polyoxyethylene sorbitan trioleate)	Included in Annex II for all food producing species	CR No 1231/06