I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Boehringer Ingelheim Vetmedica GmbH on 12 April 2006, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 16-18 May 2006 that Ingelvac CircoFLEX was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure as provided for under Regulation (EC) No. 726/2004.

During its meeting of 16-18 May 2006, the CVMP appointed Dr Maria Tollis from Italy as the Rapporteur and Dr Bruno Urbain from Belgium as the Co-Rapporteur for the assessment of the application for Ingelvac CircoFLEX.

The company Boehringer Ingelheim Vetmedica GmbH submitted an application to the EMEA on 30 January 2007 for the granting of a Community marketing authorisation for Ingelvac CircoFLEX in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 13 February 2007.

2. Steps taken for the assessment of the product

The consolidated list of questions as agreed by the CVMP during its meeting held on 12-14 June 2007 was sent to the Applicant and the clock stopped.

The list of outstanding issues as agreed by the CVMP during its meeting held on 9-11 October 2007 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 12 December 2007 a positive Opinion for the granting of a Community marketing authorisation for Ingelvac CircoFLEX.

The European Commission granted a marketing authorisation valid throughout the European Union for Ingelvac CircoFLEX on 13.02.2008.

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 and finished product:

Boehringer Ingelheim Vetmedica Inc.
2621 North Belt Highway
St. Joseph, Missouri 64506
USA

Name and address of the manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

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 THE SAFE AND EFFECTIVE USE OF THE PRODUCT

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:

Pharmacologically active substance(s)	MRL status	Comments
Carbomer	Not within the scope of Council Regulation 2377/90	
Sodium chloride	Annex II for all food producing species	