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 27 October 2006, the Committee for Veterinary Medicinal Products (CVMP) accepted on 14 December 2006 that Zactran 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 Prof. Christian Friis from Denmark as Rapporteur and Dr Gabriel Beechinor from Ireland as Co-Rapporteur for the assessment of the application for Zactran during its meeting of December 2006.

The company Merial S.A.S. submitted an application to the EMEA on 27 February 2007 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on 13 March 2007.

2. Steps taken for the assessment of the product

- The time clock for the evaluation started on 14 March 2007.
- The Rapporteur circulated the initial assessment report on 22 May 2007 and the Co-Rapporteur circulated their comments on 6 June 2007.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 11 July 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 14 May 2008 a positive Opinion for the granting of a Community marketing authorisation for Zactran.

The European Commission granted a marketing authorisation valid throughout the European Union for Zactran on 24 July 2008.

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Merial Toulouse
4 Chemin du Calquet
31057 Toulouse
France

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

To be supplied only on veterinary prescription.

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

Not applicable

D. STATEMENT OF THE MRLs

The Committee for Medicinal Products for Veterinary Use has recommended the inclusion of gamithromycin in Annex III of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Gamithromycin	Gamithromycin	Bovine	20 µg/kg 200 µg/kg 100 µg/kg	Fat Liver Kidney	Provisional MRLs expire on 1.7.2009 Not for use in animals producing milk for human consumption

Annex II of Council Regulation (EEC) No 2377/90:

Pharmacologically active substance(s)	Animal species	Other provisions
Monothioglycerol [1]	All food animal species	
Succinic Acid (E 363) [2]	All food animal species	
Glycerol Formal [3]	All food animal species	

[1] OJ No. L290 of 05.12.1995
[2] OJ No. L61 of 18.03.1995
[3] OJ No. L5 of 09.01.1997

