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 24 December 2007, the CVMP accepted at their 15-17 January 2008 meeting that EQUIOXX was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure under Article 3(3) of Regulation (EC) No. 726/2004.

The Committee for Medicinal Products for Veterinary Use appointed Dr J. Gabriel Beechinor from Ireland as Rapporteur and Dr Maria Helena Ponte from Portugal as Co-Rapporteur for the assessment of the application for EQUIOXX during its meeting of 15-17 January 2008.

The company Merial S.A.S. submitted an application to the EMEA on 4 March 2008 for the granting of a Community marketing authorisation in accordance with Article 13 (informed consent) of Directive 2001/82/EC.

The application was validated on 19 March 2008.

2. Steps taken for the assessment of the product

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on respectively 18 April 2008 and 25 April 2008. No questions were raised on the informed consent dossier.

- 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 EQUIOXX.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Merial S.A.S.
4 Chemin de Calquet
31300 Toulouse
France

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND 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. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

In accordance with Council Regulation (EEC) No 2377/90, as amended and in accordance with Article 34.4b of Regulation (EC) No 726/2004 of 31 March 2004.

Firocoxib is included in Annex I of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	
Firocoxib	Firocoxib	*Equidae*	10 µg/kg 15 µg/kg 60 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Regulation (EC) No 1729/2006 (OJ L 352 24.11.2006 p6)