I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd on 21 August 2006, the CVMP accepted on 14 September 2006 that Trocoxil 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 Karolina Törneke from Sweden as Rapporteur and Ms Cristina Muñoz Madero from Spain as Co-Rapporteur for the assessment of the application for Mavacoxib during its meeting of 12 – 14 September 2006.

The company Pfizer Ltd submitted an application to the EMEA on 27 April 2007 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 15 May 2007.

2. Steps taken for the assessment of the product

- The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 24 July 2007 and 8 August 2007 respectively.

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

- The Applicant circulated the responses to the CVMP list of questions on 21 March 2008 and the clock was restarted.

- An oral explanation was held on 18 June 2008.

- 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 16 July 2008, a positive Opinion for the granting of a Community Marketing Authorisation for Trocoxil.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

II.1 MANUFACTURING AUTHORISATIONS AND INSPECTION STATUS

Manufacturer of the active substance:

Pfizer Ltd.
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer responsible for batch release:

Pfizer (Heinrich Mack Nachf)
Heinrich-Mack-Str. 35
Illertissen
Germany

and

Pfizer Italia SPA
Via del Commercio
Localita Marino del Tronto
Ascoli Piceno
Italy

II.2 PROPOSED CONDITIONS OR RESTRICTIONS OF SUPPLY AND USE

Veterinary medicinal product subject to prescription

II.3 STATEMENT OF THE MRLs

Not applicable