I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Virbac S.A. on 27 May 2005, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 14 July 2005 (re-confirmed on 7 December 2005) that Ypozane was eligible for the centralised procedure under Article 3(2)(a) of Regulation (EC) No 726/2004, since the active substance osaterone acetate was not authorised by any Member State for use in animals on the data of entry into force of the Regulation.

The CVMP appointed Dr J. Gabriel Beechinor from Ireland as Rapporteur and Dr Liisa Kaartinen from Finland as Co-Rapporteur for the assessment of the application for Ypozane during its meeting of6-8 December 2005.

The company Virbac S.A. submitted an application to the EMEA on 7 December 2005 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 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 18-20 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 8 November 2006 a positive Opinion for the granting of a Community marketing authorisation for Ypozane.

The European Commission granted a marketing authorisation valid throughout the European Union for Ypozane on 11.01.2007.

II. A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Virbac S.A.
1ère avenue
2065 m L.I.D.
06516 Carros
France

II. 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.

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

Not applicable

II. D. STATEMENT OF THE MRLs

Not applicable

