I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by CEVA SANTE ANIMALE on 31 January 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 8-10 February 2005 that PRILACTONE 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 Mr John O'Brien (later replaced by Ms Lesley Johnston) from the United Kingdom as the Rapporteur and Dr Margarita Arboix (later replaced by Dr Cristina Muñoz Madero) from Spain as the Co-Rapporteur for the assessment of the application for PRILACTONE during its meeting of 8-10 February 2005.

The company CEVA SANTE ANIMALE submitted an application to the EMEA on 24 May 2005 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on 7 June 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 4-6 October 2005 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 17 April 2007 a positive Opinion for the granting of a Community marketing authorisation for PRILACTONE.

The European Commission granted a marketing authorisation valid throughout the European Union for PRILACTONE on 20 June 2007.

Medicinal product no longer authorised

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

Name and address of the manufacturer responsible for batch release

CEVAS SANTE ANIMALE
Z.I. Très le Bois
F-22600 Loudeac
France

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 SAFE AND EFFECTIVE USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

Medicinal product no longer authorised