## 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 1 July 1999 (initial letter on 15 July 1998), the CVMP agreed at its meeting on 17 August 1999 that Virbagen Omega was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure, as the vaccine was in accordance with Part A of the Annex to Council Regulation (EEC) 2309/93.

During its meeting of August 1999, the Committee for Veterinary Medicinal Products appointed Dr J C Rouby from France as Rapporteur and Dr H Hartmann Fries from Denmark as Co-Rapporteur for the assessment of the application.

The company Virbac S.A. submitted an application to the EMEA on 7 December 1999 for the granting of a Community marketing authorisation for Virbagen Omega in accordance with Council Regulation (EEC) No 2309/93. The application was validated on 21 December 1999.

### 2. Steps taken for the assessment of the product

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 16 February 2000 and 15 March 2000 respectively.

- The consolidated list of questions, as agreed by the CVMP during its meeting held on 18 – 20 April 2000, was sent to the Applicant and the clock was stopped.

- The manufacturing site at TORAY Industries in Japan was inspected from 24 – 26 July 2000 and it was concluded that the manufacture and quality control at that site were satisfactory.

- The Applicant circulated the responses to the CVMP list of questions on 12 April 2001 and the clock was restarted on 13 April 2001.

- The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 21 May 2001.

- The joint Rapporteur and Co-Rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the CVMP held on 12 - 14 June 2001.

- Written explanations to minor outstanding issues were provided by the applicant on 19 June 2001.

- 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 11 July 2001 a positive opinion for the granting of a Community marketing authorisation for Virbagen Omega.

 

## II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

### A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Manufacturer of the biological active substance

TORAY Industries, Inc.
2-1 Nihonbashi -muromachi 2-chome
Chuo-ku, Tokyo 103, Japan

Manufacturer responsible for batch release

Virbac S.A.
L.I.D. 1ère Avenue - 2065 m
06516 Carros, 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

Not applicable

 