

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Intervet International B.V. on 25 June 2003, the CVMP accepted on 22-24 July 2003 that Equilis Te was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) 2309/93.

The Committee for Medicinal Products for Veterinary Use appointed Dr Manfred Moos from Germany as Rapporteur and Dr Martin Illott from United Kingdom as Co-Rapporteur for the assessment of the application for Equilis Te during its meeting of 22-24 July 2003.

The application was validated on 13 January 2004.

2. Steps taken for the assessment of the product

- The procedure started on 14 January 2004.
- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 7 April 2004.
- The overall active clock days for the procedure was 183 days.
- 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 13 April 2005, a positive opinion for the granting of a Community Marketing Authorisation for Equilis Te.
- The corresponding Commission Decision was issued on 8 July 2005.

II. GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

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

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer
The Netherlands

Name and address of the manufacturer responsible for the active substance

CSL Ltd.
45 Poplar Road,
Parkville VIC 3052
Australia

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.