STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT

- The company Intervet International submitted an application to the EMEA on 2 September 1998 for the granting of a Community marketing authorisation for Pruban in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 15 September 1998.
- The centralised procedure started on 16 September 1998.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 24 November 1998 and 7 December 1998.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 13 January 1999 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions by 20 January 2000 at which point the clock was restarted.
- 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 25 February 2000.
- 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 Committee held on 8 March 2000. The Committee considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. The clock was stopped on 8 March 2000.
- The Applicant provided oral explanations on a number of outstanding issues during the meeting of the Committee held on 21 June 2000 and the clock was restarted on 22 June 2000.
- 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 19 July 2000, a positive opinion for the granting of a Community marketing authorisation for Pruban.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the active substance :

Diosynth International BV
Kloosterstraat 6
5349 AB Oss
The Netherlands

Manufacturer and assembler of the finished product:

Intervet International BV
W. de Körverstraat 35
P.O. Box 31
5830 AA Boxmeer
The Netherlands

A statement by the Ministerie van Landbouw, Natuurbeheer en Visserij dated 5 August 1997 was provided confirming that authorisation to manufacture had been granted. GMP status was confirmed by the Inspectie voor de Gezondheit of the Staatstoezicht Op De Volksgezondheid on 11 November 1999, following an inspection on 21 – 22 September 1999.

Manufacturer of the medicinal product responsible for batch release :

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

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.