I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

On 4 February 1999 the company Schering Plough Limited, United Kingdom, submitted to the EMEA a letter of intent for an application for a Community marketing authorisation for Zubrin oral lyophilisates.

During its meeting of 16 - 18 March 1999, the Committee for Veterinary Medicinal Products appointed Dr A. Wennberg from Sweden as Rapporteur and Dr G. Moulin from France as Co-Rapporteur for the assessment of the application.

2. Steps taken for the assessment of the product

The company Schering-Plough Limited submitted an application to the EMEA on 30 April 1999 for the granting of a Community marketing authorisation for Zubrin oral lyophilisate (30 mg, 50 mg, 100 mg and 200 mg) in accordance with Council Regulation (EEC) No 2309/93.

The Rapporteur and Co-Rapporteur received their copies of the dossier by 18 May 1999.

The application was validated on 18 May 1999 and the time clock for the evaluation was started on 19 May 1999.

The Rapporteur's assessment report and the Co-Rapporteur's critique on the assessment report were circulated to CVMP Members on 27 July 1999 and 11 August 1999.

The consolidated list of questions, as agreed by the CVMP during its meeting held in September 1999, was sent to the Applicant and the clock stopped on 15 September 1999.

The Applicant requested an extension to the time for the responses to the consolidated list of questions, and during the CVMP meeting of March 2000 the Committee agreed to grant the extension of five months.

The Applicant circulated the responses to the CVMP list of questions on 13 July 2000, and the clock was restarted on 14 July 2000.

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated to CVMP Members on 14 August 2000.

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions and the draft opinion were discussed during the meeting of CVMP held on 12 - 14 September 2000. The Committee considered that some of the answers provided did not satisfactorily address the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide written explanations. The clock was stopped on 13 September 2000 on day 182 of the procedure.

The Applicant provided written explanations on 10 outstanding issues on 26 September 2000 to all CVMP members.

The written explanations of the Applicant were discussed during the meeting of CVMP held on 10 – 12 October 2000 and the clock was restarted on 12 October 2000.

The joint Rapporteur and Co-Rapporteur's updated scientific overview and conclusion was circulated to CVMP Members on 13 October 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 8 November 2000 a positive opinion by consensus for the Community marketing authorisation for Zubrin.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations

Manufacturer of the medicinal product responsible for batch release:

SP Bray
Boghall Road
Bray
Co Wicklow
Ireland

The Manufacturing Authorisation was issued on 27 January 2000 by the Irish Medicines Board.

2. Conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

3. Specific obligations of the marketing authorisation holder

None

4. Statement of the MRLs

Not applicable