BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Biopure, submitted an application to the EMEA on 29 April 1998 for the granting of a Community marketing authorisation for Oxyglobin, in accordance with Council Regulation (EEC) No. 2309/93. The Committee for Veterinary Medicinal Products had appointed Dr. C. O'Sullivan as Rapporteur and Dr. G. Moulin as Co-rapporteur for the assessment of the application during its meeting of 14 – 16 October 1997. The application was validated on 12 May 1998.

2. Steps taken for the assessment of the product

- The company Biopure submitted an application to the EMEA on 29 April 1998 for the granting of a Community marketing authorisation for Oxyglobin in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 12 May 1998.

- The centralised procedure started on 13 May 1998.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 21 July 1998 and 5 August 1998.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 8-10 September 1998 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions on 11 February 1999 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 12 March 1999.

- 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 13-15 April 1999. 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 14 April 1999.

- The Applicant provided oral explanations on three outstanding quality issues during the meeting of the Committee held on 15-17 June 1999 and the clock was restarted on 17 June 1999.

- 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 14 July 1999 a positive opinion for the granting of a Community marketing authorisation for Oxyglobin.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the active substance :

Biopure Corporation
39 Hurley Street
Cambridge
MA 02141
USA

Manufacturer and assembler of the finished product:

Biopure Corporation
39 Hurley Street
Cambridge
MA 02141
USA

The Inspection Services of UK have carried out an inspection of this manufacturing site between 21-22 September 1998. The findings of the inspection are in compliance with the Community Good Manufacturing Practice requirements.

Manufacturer of the medicinal product responsible for batch release :

Dales Pharmaceuticals Ltd.
Snaygill Industrial Estate
Keighley Road,
Skipton
North Yorkshire BD23 2 RW
United Kingdom

A copy of the Manufacturing Authorisation, granted by the Medicines Control Agency on 11 January 1999, has been presented.

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.