I. BACKGROUND INFORMATION ON THE PROCEDURE

Steps taken for the assessment of the product

- The company Intervet International submitted an application to the EMEA on 2 July 1998 for the granting of a Community marketing authorisation for Incurin in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 14 July 1998.

- The centralised procedure started on 15 July 1998.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 22 September 1998 and 7 October 1998.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11 November 1998 was sent to the Applicant and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions by 18 June 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 23 July 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 17 – 18 August 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 18 August 1999.

- The Applicant provided oral explanations on a number of outstanding issues during the meeting of the Committee held on 10 November 1999 and the clock was restarted on 11 November 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 8 December 1999, a positive opinion for the granting of a Community marketing authorisation for Incurin.

II 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

(1) Manufacturer and assembler of the finished product:

NV Organon
Kloosterstraat 6
5349 AB Oss
The Netherlands

A copy of the Manufacturing Authorisation, granted by De Minister van Volksgezondheid en Milieuhygiëne on 6 October 1981 has been presented. GMP status was confirmed by the Ministry of Health, Welfare and Sport on 12 February 1998.

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.