I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Intervet International submitted on 24 July 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ibaflin gel, through the centralised procedure. After agreement by the CVMP on 12-14 June 2001, this veterinary medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CVMP were:

Rapporteur: J. Hoogland Co-Rapporteur: R. Breathnach

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 8 August 2001
- The Rapporteur's first assessment report was circulated to all CVMP Members on 16 October 2001. The Co-Rapporteur's first assessment report was circulated to all CVMP Members on 31 October 2001
- During the meeting on 4-6 December 2001 the CVMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 5 December 2001.
- The company submitted the responses to the consolidated list of questions on 6 June 2002
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CVMP Members on 16 July 2002.
- A list of outstanding issues, to be addressed at an oral explanation, were agreed by written procedure on 6 August 2002 and the clock was stopped.
- Written answers to the outstanding issues were provided by Intervet International on 16 October 2002.
- The Rapporteur provided an assessment report of the answers to the outstanding issues on 23 October 2002.
- An oral explanation was held on 13 November 2002 and the clock was restarted.
- During the meeting on 10-12 December 2002 the CVMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Ibaflin gel on 11 December 2002.
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 March 2003.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing Authorisation Holder and inspection status

Manufacturer(s) of the active substance

Chemie Uetikon
Raiffeisenstrass 4
D - 77933 Lahr
Germany

Manufacturer(s) of the finished product

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

Manufacturer responsible for batch release

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

2. Conditions or restrictions regarding supply and use

Veterinary medicinal product subject to prescription.

3. Statement of the MRLs

Not applicable.