I BACKGROUND INFORMATION ON THE PROCEDURE

I.1. Submission of the dossier

The applicant Bayer AG submitted on 4 December 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Advocate, through the centralised procedure.

After agreement by the CVMP on 11-13 September 2001, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The CVMP appointed Dr L. Kaartinen from Finland as Rapporteur and Dr L. Meisel from Portugal as Co-Rapporteur for the assessment of the application for Advocate.

Licensing status:

At the time of application the product was not authorised elsewhere.

I.1. Steps taken for the assessment of the product

- The procedure started on 19 December 2001.
- The Rapporteur's Assessment Report was circulated to all CVMP Members on 26 February 2002. The Co-Rapporteur's critique was circulated to all CVMP Members on 13 March 2002.
- During its meeting in April 2002 the CVMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 18 April 2002.
- At the April 2002 meeting of the CVMP it was confirmed that no inspection of any the manufacturing sites was required.
- The applicant submitted the responses to the CVMP consolidated List of Questions on 12 September 2002.
- The Rapporteur circulated the joint response Assessment Report on the company's responses to the List of Questions to all CVMP Members on 22 October 2002.
- During the meeting on 13 November 2002 the CVMP agreed with the joint (Co)Rapporteur's recommendation that no Oral Explanation was required and agreed a List of Outstanding Issues.
- The applicant submitted a Letter of Commitment regarding the one quality follow-up measure dated 15 November 2002. Written responses to the List of Outstanding Issues were provided by the applicant on 18 and 22 November 2002.
- During its meeting in December 2002, the CVMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for the granting of a marketing authorisation for Advocate 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 Decision on 2 April 2003.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

II.1. Manufacturing Authorisation Holder and inspection status

Manufacturers of the active substances:

Imidacloprid

Bayer AG,
D-41538 Dormagen,
Germany

Moxidectin

Fort Dodge Animal Health,
Division of Wyeth Lederle S.p.a.,
Via Franco Gorgone,
6A Zona Industriale,
I-9503 Catania,
Italy

Manufacturer of the finished product and responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH,
Projensdorfer Str. 324,
D-24106 Kiel,
Germany

Manufacturing Authorisation issued on 3 June 1997 by Medicines Control Agency, Schleswig-Holstein, Germany.

II.2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

II.3. Statement of the MRLs

Not applicable.