I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Intervet International submitted an application to the EMEA on 4 October 1996 for the granting of a Community marketing authorisation for Nobilis IB 4-91 in accordance with Council Regulation (EEC) No 2309/93. The application was validated on 15 October 1996.

During its meeting of 6-7 February 1996, the Committee for Veterinary Medicinal Products appointed Dr J M Rutter as Rapporteur and Prof J Boisseau as Co-rapporteur for the assessment of the application.

The assessment team consisted of the following experts :

Dr D Fawthrop
Dr J Rouby
Dr M Guittet

Licensing status:

A Provisional Marketing Authorisation has been issued by the Veterinary Medicines Directorate in the UK and an Authorisation for Temporary Usage has been granted in France.

2. Steps taken for the assessment of the product

_ The company Intervet International submitted an application to the EMEA on 4 October 1996 for the granting of a Community marketing authorisation for Nobilis IB4-91 in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 15 October 1996.

_ The centralised procedure started on 16 October 1996.

_ The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 24 December 1996.

_ The consolidated list of questions as agreed by the CVMP during its meeting held on 11-12 February 1997 was sent to the Applicant and the clock stopped.

_ The Applicant circulated the responses to the CVMP list of questions by 15 August 1997 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 15 September 1997.

_ 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 14-16 October 1997.

_ 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 12 November 1997 a positive opinion for the granting of a Community marketing authorisation for Nobilis IB 4-91.

_ The Marketing Authorisation Holder submitted two variations on 5 February 1999 to add a 500 dose presentation and a multi-pack presentation of 10 vials of 500 doses. The variation applications were validated and the clock started on 13 February 1999. Having received recommendations from the Rapporteur, the EMEA accepted the two variations and notified the European Commission and the Marketing Authorisation Holder on 8 March 1999.

A. MANUFACTURING AUTHORISATION HOLDER

Manufacturer responsible for batch release

Intervet International
Wim de Körverstraat 35,
5831 AN Boxmeer,
The Netherlands

Manufacturing Authorisation issued on 30 May 1995

by

Ministerie van Landbouw, Natuurbeheer en Visserij
The Hague
The Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC[1] Member States prohibit or/ may prohibit the import, sale, supply and/or use of Nobilis IB 4-91 on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programs for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals
b) the disease to which the product is intended to confer immunity is largely absent from the territory.

D. STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Not applicable

[1] Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC an the approximation of laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary products (OJ N°L 373 of 31.12.1990)