I BACKGROUND INFORMATION TO THE PROCEDURE

1. Submission of the dossier

On 4 January 2000, Intervet International BV submitted an application to the EMEA for the granting of a Community marketing authorisation for Nobilis OR inac in accordance with Council Regulation (EEC) No 2309/93. The time clock for the evaluation was started on 19 January 2000 (Day 1).

The Rapporteur's assessment report and the Co-Rapporteur's critique on the assessment report were circulated to CVMP Members on 28 March 2000 and 12 April 2000. A consolidated list of questions was adopted by the CVMP during its meeting held in May 2000 and the clock for the evaluation was stopped on 17 May 2000 (Day 120).

On 16 November 2000, the Applicant circulated responses to the CVMP list of questions, and the clock was restarted on 17 November 2000 (Day 121).

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated to CVMP Members on 15 December 2000 and was discussed during the meeting of CVMP held on 9 – 11 January 2001. The Committee considered that some of the answers provided did not satisfactorily address the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral and written explanations. The clock was stopped on 10 January 2001 of the procedure (Day 175).

The Applicant provided written explanations on 29 outstanding issues on 26 March 2001 to all CVMP members. Oral and written explanations of the Applicant were discussed during the meeting of CVMP held on 18 – 19 April 2001 and the clock was restarted on 19 April 2001 (Day 176).

The joint Rapporteur and Co-Rapporteur's updated scientific overview and conclusion was circulated to CVMP Members on 20 April 2001. At the May 2001 meeting, the CVMP considered that there remained some outstanding issues mainly related to compliance with TSE requirements and the clock was stopped exceptionally on 16 May 2001 (Day 204).

In September 2002, the Applicant provided answers to the outstanding issues and a joint assessment report by the Rapporteur and Co-Rapporteur on the answers was circulated to all CVMP members. On 1 October 2002, the clock was re-started (Day 205).

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 2 October 2002 a positive opinion for the Community marketing authorisation for Nobilis OR inac. One CVMP member expressed a divergent opinion.

II GENERAL CONDITIONS FOR THE MAKETING AUTHORISATION

Manufacturer(s) of the biological active substance
Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release

Intervet International
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturing Authorisation issued on 5 August 1997 by Ministrie van Landbouw, Natuurbeheelf en Visserij, NL.

Conditions of the Marketing Authorisation

Veterinary medicinal product subject to prescription.

Prohibition of sale, supply and/or use

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes 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 veterinary medicinal product is intended to confer immunity is largely absent from the territory.

Statement of MRLs

- For the active principle of biological origin intended to produce immunity, Council Regulation (EEC) No 2377/90 does not apply.

- The adjuvants and excipients listed are included in Annex II of Council Regulation (EEC) No 2377/90.

Pharmacologically active substance	Animal Species	Other provisions
Mineral hydrocarbons, low to high viscosity including microcristalline waxes, approximately C10-C60; aliphatic, branched aliphatic and alicyclic compounds.	All food producing species	Excludes aromatic and unsaturated compounds
Polysorbate 80	All food producing species	
Sodium chloride	All food producing species	

- Sorbitan oleate (E 494), Potassium dihydrogen phosphate (E 340), Disodium hydrogen phosphate (E 339) and Potassium chloride (E 508) are approved as additives in foodstuffs for human consumption and therefore covered by Annex II of Council Regulation (EEC) No. 2377/90 for substances with an E- number[1] (with the exception of preservatives listed in part C of Annex III to Council Directive 95/2/EC[2].).

[1] OJ No L272 of 25.10.1996, p. 2
[2] OJ No L 61 of 18.3.1995, p. 1