Steps taken for the assessment of the product

- Porcilis Porcoli **(originally called Nobi-vac Porcoli)** is a veterinary vaccine which was authorised in some Member States of the European Community after 1 July 1987 without going through the concertation procedure, although it is a biotechnology derived product which fell under the scope of list A of the Annex to Council Directive 87/22/EEC of 22.12.86. Once this was known, the Commission informed the Member States that the authorisation was not valid according to the terms of EC legislation and requested that a concertation procedure in accordance with Directive 87/22/EEC be initiated, as had been done for the other products in the same situation.

- On 25 March 1994, Intervet International B.V. submitted an application to Belgium, France, Germany, Greece, Ireland, Italy, The Netherlands, Portugal, Spain and The United Kingdom for Porcilis Porcoli. A concertation procedure (No. 24) was initiated on 1 April 1994.

- Dr H H Lensing was appointed as Rapporteur, and an initial assessment report was circulated to the members of the Committee for Veterinary Medicinal Products (CVMP) on 28 April 1994. On 6 July 1994, a consolidated list of questions was sent by the CVMP to the applicant and the clock stopped at that point.

- In accordance with Article 2 of Directive 93/41/EEC, the application of Intervet International B.V. was transferred to the EMEA on 1 January 1995.

- Before 1 January 1995, the product was authorised in the following countries: Belgium, Chile, Cyprus, France, Germany, Greece, Hong Kong, Hungary, Ireland, Italy, Kenya, Mauritius, Mexico, The Netherlands, Peru, The Philippines, Poland, Portugal, Slovenia, South Africa, Spain, Switzerland, Taiwan, Thailand, United Kingdom, Venezuela and West Malaysia.

- During its meeting on 22-23 January 1995, the CVMP confirmed Dr H H Lensing as Rapporteur. The evaluation team was composed of one expert from The Netherlands and one from the United Kingdom. On 1 April 1995, on receipt of the response to the CVMP consolidated list of questions, the procedure was restarted. On 23 May 1995 the Rapporteur's assessment report was circulated to CVMP members.

- During its meeting on 21-22 June 1995, the CVMP was not in the position to reach an opinion on the product. The concern related to the inadequacy of the applicant's response to certain questions, on matters of Quality. It was agreed that the applicant should be given one more opportunity to reply to the outstanding questions; within four weeks of being informed by the EMEA. Meanwhile the Committee reviewed, amended and eventually adopted the Summary of Product Characteristics (SPC), the label and the package insert for Porcilis Porcoli.

- Additional information concerning the ouststanding Quality issues were received on 24 July 1995.

At its meeting on 26-28 July 1995, as the outstanding Quality issues had been satisfactorily addressed by the applicant, and with the exception of 8 of its members who were not in favour, the CVMP adopted a positive opinion for the granting of a Community marketing authorisation for Porcilis Porcoli for each presentation.

I GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A – MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN BOXMEER

Authorisation delivered by Ministerie van Landbouw, Natuurbeheer en Visserij, Directoraat-Generaal Landelijke Gebieden en Kwaliteitszorg, Veterinary Dienst, The Hague, The Netherlands on 05/02/92.

B - CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C - PROHIBITION OF SALE, SUPPLY AND/OR USE

Not Applicable.

D - STATEMENT OF THE MRLs.

Not applicable

