Steps taken for the assessment of the product

- On 21 February 1996 the company Virbac requested scientific advice for a modified live vaccine for the oral vaccination of foxes against rabies. Scientific advice regarding quality, safety and efficacy issues was provided by CVMP on 23 July 1996.

- The CVMP accepted in November 1997 that Virbac was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure as provided for under Part A of the Annex to that Regulation.

- The company Virbac submitted an application to the EMEA on 11 February 1998 for the granting of a Community marketing authorisation for Rabigen SAG2 in accordance with Council Regulation (EEC) No 2309/93.

- The application was validated on 17 March 1998, the evaluation was started on 24 March 1998.

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 27 May 1998 and 5 June 1998.

- The consolidated list of questions as agreed by the CVMP during its meeting in July 1998 was sent to the Applicant on 8 July 1998 at which time the clock was stopped (day 106 of the procedure).

- The Applicant circulated the responses to the CVMP list of questions for Rabigen SAG2 by 18 June 1999 at which point the clock was restarted (day 107 of the procedure).

- The joint Rapporteur and Co-Rapporteur's 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 23 July 1999

- 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 18 August 1999. The CVMP considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. The clock was stopped on 18 August 1999 (day 168 of the procedure).

- The Applicant provided oral explanations on 10 November 1999 during the meeting of the Committee held on 9 – 11 November and the clock was restarted on 11 November 1999 (day 169 of the procedure).

- 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 8 December 1999 a positive opinion for the granting of a Community marketing authorisation for Rabigen SAG2**.**

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the active substance:

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros
France

Manufacturer and assembler of the finished product:

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros
France

Manufacturer of the medicinal product responsible for batch release:

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros
France

Manufacturing Authorisation issued on December 22 1997 by the Ministère de la solidarité, de la santé et de la protection sociale – Direction de la pharmacie et du medicament - République Française.

2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

Restricted to duly designated competent administrative authorities.

STATEMENT OF THE MRLs WHICH MAY BE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Not applicable