

Steps taken for the assessment of the product

Further to the submission of a letter of intent by Intervet International BV on 14 November 2000, the Committee for Veterinary Medicinal Products agreed during its meeting of 5-7 December 2000 that Nobivac Bb was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 2309/93. The name originally proposed by the Applicant (“Nobivac Bb cat”) was changed during the evaluation into “Nobivac Bb” with the qualifier “for cats” being allowed to use in the product literature.

During its meeting of 5-7 December 2000, the CVMP appointed Mr. S. Dean from the United Kingdom as Rapporteur and Prof. M. Moos from Germany as Co-rapporteur for the assessment of the application for Nobivac Bb. Dr. D. Mackay replaced Mr. S. Dean further to the CVMP meeting of 9-11 January 2001.

The company Intervet International BV submitted an application to the EMEA on 31 January 2001 for the granting of a Community marketing authorisation for Nobivac Bb in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 13 February 2001 and the time clock for the evaluation was started on 14 February 2001.

The Rapporteur’s Assessment report and the Co-Rapporteur’s critique on the assessment report were circulated to CVMP Members by 24 April 2001 and 9 May 2001.

The consolidated list of questions, as agreed by the CVMP during its meeting held in June 2001, was sent to the Applicant and the clock stopped on 13 June 2001.

The Applicant circulated the responses to the CVMP list of questions on 13 December 2001, and the clock was restarted on 14 December 2001.

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated to CVMP Members on 22 January 2002.

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions and the draft opinion were discussed during the meeting of CVMP held on 12 – 14 February 2002. 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 written and oral explanations. The clock was stopped on 13 February 2002 on day 182 of the procedure.

The Applicant provided written explanations on outstanding issues on 22 April 2002 to all CVMP members.

The Applicant gave an oral explanation on 2 outstanding issues on 15 May 2002.

The written and oral explanations of the Applicant were discussed during the meeting of CVMP held on 14-16 May 2002 and the clock was restarted on 16 May 2002.

The Applicant provided a letter of commitment on 24 May 2002.

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 June 2002 a positive opinion for the Community marketing authorisation for Nobivac Bb.