

## **STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT**

- The CVMP accepted on 13-15 October 1998 that Purevax FeLV was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part A of the Annex to Council Regulation (EEC) 2309/93.
- The company Merial submitted an application to the EMEA on 23 December 1998 for the granting of a Community marketing authorisation for Purevax FeLV in accordance with Council Regulation (EEC) No 2309/93.
- The application was validated on 12 January 1999 and the clock started on 13 January 1999.
- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 23 March 1999 and 7 April 1999.
- The consolidated list of questions as agreed by the CVMP during its meeting held 11 – 13 May 1999 was sent to the Applicant on 12 May 1999 at which time the clock was stopped.
- The Applicant circulated the responses to the CVMP list of questions for Purevax FeLV by 9 September 1999 at which point the clock was restarted.
- The joint Rapporteur and Co-rapporteur's assessment report on the responses to the consolidated list of questions were circulated to all CVMP Members on 13 October 1999.
- The Applicant provided clarification of outstanding issues at an oral explanation before the Committee on 7 December 1999.

## GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

### 1. Manufacturing authorisations

#### Manufacturer of the active substance :

Merial, Laboratory of Lyon Gerland  
254, rue Marcel Mérieux  
69007 Lyon FRANCE

#### Manufacturer and assembler of the finished product:

Merial, Laboratory of Lyon Gerland  
254, rue Marcel Mérieux  
69007 Lyon FRANCE

also Merial, Laboratory of Portes des Alpes & Laboratory of Lentilly

#### Site where batch release takes place:

MERIAL  
Laboratoire Porte des Alpes  
Rue de l'AviationF-69800 SAINT PRIEST  
FRANCE

### 2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.