I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd, the CVMP accepted on 8 December 2005 that Slentrol was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised procedure under Regulation 726/2004.

The Committee for Medicinal Products for Veterinary Use appointed Dr. Karolina Törneke from Sweden as Rapporteur and Dr Anja Holm from Denmark as Co-Rapporteur for the assessment of the application for Slentrol during its meeting of 8-10 March 2005.

The company Pfizer Ltd submitted an application to the EMEA on 11 February 2006 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 21 February 2006.

2. Steps taken for the assessment of the product

- The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 2 May 2006 and 17 May 2006 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 21 June 2006 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 17 November 2006 and the clock was restarted.
- 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 14 February 2007, a positive Opinion for the granting of a Community Marketing Authorisation for Slentrol.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

II.1 MANUFACTURING AUTHORISATIONS AND INSPECTION STATUS

Manufacturer of the active substance:

Pfizer Ltd
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer responsible for batch release
Pfizer Service Company
10 Hoge Wei
1930 Zaventem
Belgium

II.2 PROPOSED CONDITIONS OR RESTRICTIONS OF SUPPLY AND USE

Veterinary medicinal product subject to prescription.

II.3 STATEMENT OF THE MRLs

Not applicable