I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd on 15 October 2003, the Committee for Veterinary Medicinal Products (CVMP) accepted during its meeting from 11 – 13 November 2003 that Convenia 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 CVMP appointed Prof. Dr Reinhard Kroker from Germany as Rapporteur and Dr Liisa Kaartinen from Finland as Co-Rapporteur for the assessment of the application for Convenia during its meeting of 11 – 13 November 2003.

The company Pfizer Ltd submitted an application to the EMEA on 27 April 2004 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.

The procedure started on 12 May 2004.

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 21 July 2004 and 4 August 2004 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held in September 2004 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 20 October 2005 and the clock was restarted.
- The joint Rapporteur and Co-Rapporteur 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 4 November 2005.
- An Oral Explanation was provided by the Applicant to the CVMP on 15 March 2006.
- 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 20 April 2006, a positive Opinion for the granting of a Community Marketing Authorisation for Convenia.
- The corresponding Commission Decision was issued on 19 June 2006.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

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

Name and address of the manufacturer responsible for batch release:

Pfizer Italia s.r.l.
S.S. 156 Km 50
04010 Borgo San Michele
Latina
Italy

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

