I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Air Liquide Santé International on 21 January 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 9 February 2005 that Medicinal Oxygen Air Liquide Santé was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 726/2004.

The CVMP appointed Dr J. Gabriel Beechinor from Ireland as Rapporteur and Mr Peter Ekström from Sweden as Co-Rapporteur for the assessment of the application for Medicinal Oxygen Air Liquide Santé during its meeting of 8-10 February 2005.

The company Air Liquide Santé International submitted an application to the EMEA on 7 December 2005 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No No 726/2004.

The application was validated on 21 December 2005.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 19 April 2006 was sent to the Applicant and the clock stopped.
- 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 11 October 2006 a positive Opinion for the granting of a Community marketing authorisation for Medicinal Oxygen Air Liquide Santé.

The European Commission granted a marketing authorisation valid throughout the European Union for Medicinal Oxygen Air Liquide Santé on 20.12.2006.

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Air Liquide Santé France
Zone Industrielle Est
BP 34
F-54181 Heillecourt
France

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 SAFE AND EFFECTIVE USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

