I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Cyton Biosciences Ltd.** on 3 December 2004, the Committee for Veterinary Medicinal Products (CVMP) accepted on 13 January 2005 that **Suprelorin** was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Regulation (EC) No. 726/2004.

The CVMP appointed **Dr Anja Holm** from **Denmark** as Rapporteur and **Dr Leonor Meisel** from **Portugal** as Co-Rapporteur for the assessment of the application for **Suprelorin** during its meeting of 11 – 13 January 2005.

The company **Cyton Biosciences Ltd.** submitted an application to the EMEA on **6 September 2005** for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on **20 September 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 17 – 19 January 2007 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 14 March 2007 a positive Opinion for the granting of a Community marketing authorisation for Suprelorin.
- The applicant requested a re-examination of the Opinion and a revised Opinion was granted on 15 May 2007.

The European Commission granted a marketing authorisation valid throughout the European Union for Suprelorin on 10/07/2007.

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

Name and address of the manufacturer responsible for batch release

Brecon Pharmaceuticals Ltd.
Pharos House
Wye Valley Business Park
Hay-on-Wye
Breconshire,
Hereford HR3 5PG
United Kingdom

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

Veterinary medicinal product subject to prescription.

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

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.