I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by S-P Veterinary on 15 February 2001, the Committee for Veterinary Medicinal Products (CVMP) accepted at its meeting held on 13-15 March 2001 (and then reconfirmed on 8 December 2005) that Posatex was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Article 3(2)(a) of Regulation (EC) No. 726/2004.

The CVMP appointed Dr Michael Holzhauser-Alberti from France as Rapporteur and Ms Ruth Kearsley from United Kingdom as Co-Rapporteur for the assessment of the application for Posatex during its meeting of 13-15 March 2001.

The company S-P Veterinary submitted an application to the EMEA on 3 October 2006 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on 17 October 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 3 January 2007 and 19 January 2007 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 13-15 February 2007 was sent to the Applicant and the clock stopped.
- The joint Rapporteur and Co-Rapporteur assessment report on the responses submitted on 19 October 2007 to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 27 November 2007.
- An oral explanation was held on 12 March 2008.
- 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 15 April 2008 a positive Opinion for the granting of a Community marketing authorisation for Posatex.
- The corresponding Commission Decision was issued on 23 June 2008.

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

S-P Bray
Boghall Road
County Wicklow
Ireland

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

To be supplied only on veterinary prescription.

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.