I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Pharmacia submitted on 28 October 2002 an application for a Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for NAXCEL, through the centralised procedure. With the transfer of the marketing Authorisation from Pharmacia to Pfizer in August 2003, the responses to the list of questions were submitted by Pfizer.

After agreement by the CVMP on 14 – 16 May 2002, this veterinary medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 due to the manufacturing process, which demonstrates a significant technical advance.

The Rapporteur and Co-Rapporteur appointed by the CVMP were Gérard Moulin as Rapporteur and Reinhard Kroker as Co-Rapporteur. The Rapporteurship changed during the procedure to Marie-Anne Botrel and subsequently to Michael Holzhauser-Alberti.

Licensing status (outside EEA):

At the time of approval of the application on 19 May 2005, the product had been given a Marketing Authorisation in the USA (under the name “EXCEDE for swine”).

2. Steps taken for the assessment of the product

- The procedure started on 13 November 2002.
- The Rapporteur's first assessment report was circulated to all CVMP Members on 21 January 2003. The Co-Rapporteur's first assessment report was circulated to all CVMP Members on 5 February 2003.
- During the meeting on 11 March 2003 the CVMP agreed on the consolidated list of questions to be sent to the company.
- The company submitted the responses to the consolidated list of questions on 9 September 2004.
- The rappporteurs circulated the joint response assessment report on the company’s responses to the list of questions to all CVMP Members on 19 October 2004.
- Oral and written explanations to outstanding issues were provided by the applicant on 10 December 2004.
- During the January 2005 meeting, the CVMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to NAXCEL on 11 January 2005.
- At their February 2005 meeting, the CVMP confirmed the positive opinion further to an appeal by the Applicant regarding a minor change of the wording of the Summary of Product Characteristics (SPC).
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 May 2005.

