1. Submission of the dossier

The company Solvay-Duphar submitted an application to the EMEA on 2 September 1996 for the granting of a Community marketing authorisation for Suvaxyn Aujeszky 783+O/W in accordance with Council Regulation (EEC) No 2309/93. On 16 September 1996 the validation was stopped and the company informed that additional particulars were required in accordance with Article 28.2 of that Council Regulation, which were submitted on 17 October 1996. The application was validated on 17 October 1996. Fort Dodge Animal Health Holland has since taken over all responsibilities of Solvay-Duphar for the application and is the recognised marketing authorisation holder.

2. Steps taken for the assessment of the product

1. The Rapporteur and Co-Rapporteur received their copies of the dossier on 17 October 1996 and 18 October 1996 respectively.

2. The centralised procedure started on 19 October 1996.

3. The Rapporteur and Co-Rapporteur's assessment report was circulated to the CVMP Members on 23 December 1996.

4. The consolidated list of questions, as agreed by the CVMP during its meeting held on 12 -14 February 1997, was sent to the applicant on 14 February 1997 at which time clock was stopped for 6 months. The applicant requested to extend the clock stop for a further 5 months to conduct certain studies at a suitable site to answer the CVMP list of questions.

5. The applicant circulated the responses to the CVMP list of questions on 8 January 1998 at which point the time clock was restarted.

6. 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 the CVMP Members on 3 February 1998.

7. The joint Rapporteur and Co-rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 10 – 12 March 1998.

8. 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 8 April 1998 a positive opinion for the granting of a Community marketing authorisation for Suvaxyn Aujeszky 783+O/W by consensus.

A. MANUFACTURING AUTHORISATION HOLDER(S)

Manufacturer(s) responsible for batch release

Fort Dodge Animal Health Holland
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

Manufacturing Authorisation issued on 9 February 1993 by Ministerie van Landbouw, Natuurbeheer en Visserij, The Netherlands.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC[1] Member States prohibit or/ may prohibit the import, sale, supply and/or use of Suvaxyn Aujeszky 783 + OW on the whole or part of their territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals
b) the disease to which the product is intended to confer immunity is largely absent from the territory.

D. STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Animal Species	Other provisions
Aluminiumhydroxide[2]	All food-producing species	
Disodiumhydrogenphosphate[3]		
Mannitol[4]		
Mineral oil [5]		
Polysorbate[6]		
Sodiumhydrogenphosphate[7]		
Thiomersal[8]		

[1] Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC an the approximation of laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary products (OJ N°L 373 of 31.12.1990)

[2] OJ No. L 290 of 5.12.95
[3] OJ No. L 272 of 25.10.96
[4] OJ No. L 272 of 25.10.96
[5] OJ No. L 291 of 6.12.95
[6] OJ No. L 272 of 25.10.96
[7] OJ No. L 272 of 25.10.96
[8] OJ No. L 110 of 26.04.97