I BACKGROUND INFORMATION ON THE PROCEDURE

1. Scientific advice

On 27 June 1996, the company Biokema requested Scientific Advice pursuant to article 51 (j) of Council Regulation (EEC) No 2309/93.

During its meeting held on 17-18 September 1996, the Committee for Veterinary Medicinal Products (CVMP) appointed Prof. M. Moos as co-ordinator.

Having considered proposals of the co-ordinator, the CVMP agreed during its meeting held on 10-11 December 1996 on recommendations considering the health status of donor cows, the potential risk of transmission of BSE and the challenge tests to be used to demonstrate the efficacy of the product.

2. Submission of the dossier

The company Biokema submitted an application to the EMEA on 3 June 1997 for the granting of a Community marketing authorisation for Serinucoli in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 17 June 1997.

During its meeting of February 1997, the Committee for Veterinary Medicinal Products appointed P-P. Pastoret as Rapporteur and M. Moos as Co-Rapporteur for the assessment of the application.

The Rapporteur and Co-Rapporteur received their copies of the dossier on 6 June 1997 and 4 June 1997 respectively. The time clock for the evaluation was started on 18 June 1997.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eudra.org http://www.eudra.org/emea.html

3. Steps taken for the assessment of the product

1. The Rapporteur and Co-Rapporteur received their copies of the dossier on 6 June 1997 and 4 June 1997 respectively. The application was validated on 17 June 1997.

2. The centralised procedure started on 18 June 1997.

3. The Rapporteur's assessment report was circulated to the CVMP Members on 26 August 1997.

4. The Co-Rapporteur's critique on the assessment report was circulated to the CVMP Members on 10 September 1997.

5. The CVMP at its meeting on September 9-11 1997 adopted the recommendation of the Rapporteur and Co-Rapporteur that GMP inspection of the manufacturing facility in Switzerland should be undertaken.

6. An inspection took place by the competent authority of France (being the EU importing country) accompanied by the Rapporteur and Co-Rapporteur on 18-19 December 1997 and a favourable opinion was given.

7. The consolidated list of questions, as agreed by the CVMP during its meeting held on 14 -16 October 1997, was sent to the Applicant on 16 October 1997 at which time the clock was stopped for 6 months. The Applicant requested an extension to the clock stop for a further 6 months to conduct certain studies required to answer the CVMP list of questions.

8. The Applicant circulated the responses to the CVMP list of questions on 11 June 1998 at which point the time clock was restarted.

9. 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 10 July 1998.

10. 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 8 – 10 September 1998. At day 209 of the procedure, there having been no meeting of CVMP in August 1998, the CVMP invited the applicant to provide oral explanations on several aspects of the dossier requiring clarification. The time clock was stopped on 8 September 1998.

11. As requested the Applicant provided oral explanations on several aspects of the dossier requiring clarification on 8 December 1998. On 9 December 1998 the time clock was restarted.

12. 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 9 December 1998 a positive opinion for the granting of a Community marketing authorisation for Serinucoli by a majority of 19 to 8 CVMP members, the latter having expressed divergent positions which are appended to this assessment report.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations

Manufacturer of the medicinal product responsible for batch release:

Merial Laboratoire de Gerland
Av. Marcel Mérieux 254
69342 Lyon Cedex 07
France

A Manufacturing Authorisation certificate was issued on 26 April 1996 by the 'Agence Nationale du Medicament Veterinaire', BP 203-35202 Fougeres, France.

Manufacturer of the active substance:

Biokema SA
2 Chemin de la Chatanérie
1023 Crissier-Lausanne
Switzerland

A Manufacturing Authorisation certificate was issued on 22 March 1996 by the Institute of Virology and Immunoprophylaxis, on behalf of the Federal Veterinary Office of Switzerland.

The above mentioned production facilities were subject to GMP inspection on 17 – 18 December 1997 and conform to the principles and guidelines of GMP as required by Council Directive 81/851/EEC.

2. Conditions or restrictions of supply and use

According to Article 4 of Council Directive 90/677/EEC[1] Member States may prohibit the import, sale, supply and/or use of Serinucoli 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 elimination 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.

3. Specific obligations of the marketing authorisation holder

None

[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)

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
Calcium chloride[2]	All food-producing species	
Sodium chloride [3]		
Lactic acid [4]		
Sodium hydroxide [5]		
Sodium methyl hydroxybenzoate [6]		
Sodium propyl hydroxybenzoate [7]		
Sodium propionate [8]		
Propionic acid[9]		

[2] OJ No. L 110 of 17.05.95
[3] OJ No. L 272 of 25.10.96
[4] OJ No. L 108 of 29.04.94
[5] OJ No. L 272 of 25.10.96
[6] OJ No. L 272 of 25.10.96
[7] OJ No. L 272 of 25.10.96
[8] OJ No. L 272 of 25.10.96
[9] OJ No. L 272 of 25.10.96