I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merial submitted on 26 October 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for ProteqFlu, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CVMP:

Rapporteur: J.C. Rouby Co-Rapporteur: M. Moos

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 14 November 2001
- The Rapporteur's first assessment report was circulated to all CVMP Members on 22 January 2002. The Co-Rapporteur's first assessment report was circulated to all CVMP Members on 6 February 2002
- During the meeting on 12-14 March 2002 the CVMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 13 March 2002.
- The company submitted the responses to the consolidated list of questions on 15 August 2002.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CVMP Members on 20 September 2002.
- During the meeting on 12-14 November 2002 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 ProteqFlu on 13 November 2002.
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 6 March 2003.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

Manufacturing authorisations and inspection status

Manufacturer of the active substance:

Merial, Laboratory of Lyon Gerland
254, Avenue Marcel Mérieux, 69007 Lyon, France

Manufacturing Authorisation issued on 14 August 1997 by the National Agency for Veterinary Medicinal Products, France.

Manufacturer responsible for batch release:

MERIAL, Laboratoire Porte des Alpes
Rue de l'Aviation, F-69800 Saint Priest, France

Manufacturing Authorisation issued on 14 August 1997 by the National Agency for Veterinary Medicinal Products, France.

Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.

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 ProteqFlu 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.

[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)

Statement of the MRLs

The following substances contained in the final product are included in Annex II of Council Regulation (EEC) No 2377/90:

Pharmacologically active substance(s)	Animal Species	Other provisions	Comments
Sodium chloride	All food producing species		CR No. 2796/95
Disodium phosphate	All food producing species		Approved food additive (E339), CR No 2034/96
Monopotassium phosphate	All food producing species		Approved food additive (E340), CR No 2034/96

Other substances contained in the final product:

Substance(s)	**MRL status**	**Comments**
Sucrose	Not falling within scope of CR No 2377/90	Naturally occurring Carbohydrates
Collagen hydrolysate	Not falling within scope of CR No 2377/90	
Casein hydrolysate	Not falling within scope of CR No 2377/90	
Water for injections	Not falling within scope of CR No 2377/90	
Carbomer	Not falling within scope of CR No 2377/90	
Gentamicin	Included in Annex I of CR 2377/90 for bovine and porcine species	Not considered pharmacologically active at the doses administered to the animals