I. STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT

Further to the submission of a letter of intent by Intervet International B.V. on 16 May 2002, the CVMP accepted that Equilis StrepE was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part A of the Annex to Council Regulation (EEC) 2309/93.

During its meeting of 9-11 July 2002, the Committee for Veterinary Medicinal Products appointed Prof M. Moos from Germany as Rapporteur and Dr H. Hartmann-Fries (later replaced by Dr A. Holm) from Denmark as Co-rapporteur for the assessment of the application for Equilis StrepE.

- Intervet International B.V. submitted the application to the EMEA on 28 October 2002 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.

- The application was validated on 12 November 2002 and the assessment was concluded within the 210 day timeframe. The clock was stopped for a total of 243 days during the procedure.

- Consultation with the GMO Authorities on Part IIH of the dossier was undertaken in line with Duirective 2001/18/EC.

- 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 10 February 2004, a positive opinion for the granting of a Community marketing authorisation for Equilis StrepE.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Manufacturer of the active substance and responsible for batch release:

Intervet International B.V
Wim de Körverstraat 35
NL-5831 AN Boxmeer
The Netherlands

Manufacturing Authorisation issued on 18 May 2001 by Ministerie van Landbouw, The Netherlands.

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING 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 Equilis StrepE 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.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLS

Substance	MRL status	Comments
Streptococcus equi strain	Not within the scope of Council Regulation (EC) 2377/90	Active principles of biological origin intended to produce active or passive immunity are not within the scope of the Regulation[1].

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[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)

Pancreatic Digest of Casein	Not within the scope of Council Regulation (EC) 2377/90	CVMP has previously considered that casein hydrolysates are not within the scope of the Regulation
Sucrose	Not within the scope of Council Regulation (EC) 2377/90	Carbohydrates naturally occurring are considered not within the scope of the Regulation
Gelatin	Not within the scope of Council Regulation (EC) 2377/90	
Water for injections	Not within the scope of Council Regulation (EC) 2377/90	